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Lesion index: a novel guide in the path of successful pulmonary vein isolation

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Abstract

Purpose Previous studies indicate force time integral (FTI) as a radiofrequency (RF) lesion quality marker, while not considering power supply. Tacticath™ Quartz catheter provides Lesion index (LSI), a lesion quality marker derived by contact force (CF), power supply, and RF time combined. Our aim is to assess LSI and FTI correlation and a LSI-related cutoff of atrial fibrillation (AF) recurrences 12 months after pulmonary vein isolation (PVI).

Methods We retrospectively enrolled 37 patients who underwent RF ablation using Tacticath™ Quartz catheter. AF recurrence rate was evaluated 3, 6, and 12 months after PVI procedure.

Results AF recurrence was detected in 32% of patients. FTI mean value was significantly lower in left superior pulmonary vein (LSPV: 256 ± 86 gs vs 329 ± 117 gs, $p = 0.05$) and right inferior pulmonary vein (RIPV: 253 ± 128 gs vs 394 ± 123 gs $p = 0.006$) in patients with AF recurrences; no significant differences were found in right superior pulmonary vein (RSPV) and left inferior pulmonary vein (LIPV). LSI instead was significantly higher for all veins in patients without AF recurrences: LSPV (5.2 ± 0.7 vs 4.6 ± 0.8, $p = 0.03$), LIPV (5.0 ± 0.8 vs 4.5 ± 0.6, $p = 0.04$), RSPV (5.5 ± 0.6 vs 5.1 ± 0.6, $p = 0.05$), and RIPV (5.5 ± 0.7 vs 4.7 ± 0.8, $p = 0.006$). Receiver operator characteristic curve suggests 5.3 as LSI overall cutoff value predicting freedom from disease at 1-year follow-up.

Conclusions Our preliminary data suggest that a LSI mean value higher than 5.3 can be considered a good predictor of AF freedom at 1-year follow-up.

Keywords Atrial fibrillation · Catheter ablation · Contact force · Force time integral · Lesion index · Predictive lesion index

1 Introduction

The efficacy of atrial fibrillation (AF) treatment is still controversial and is limited by the difficulty of obtaining a long-lasting isolation of pulmonary veins (PVs) often responsible for AF recurrences [1–5].

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The effectiveness of lesions produced during ablation greatly depends on the contact between the catheter tip and the endocardium [6, 7]. Currently, to assess this contact, ablation catheters are endowed with sensors able to measure the force applied (contact force, CF). The applied mechanical force feedback can be crucial in determining the effective persistence of lesions [8].

Recent studies have shown that an ablation guided by force sensors allows for a better isolation of PVs [9–11]. In cases of paroxysmal AF, CF is shown to be strongly related to the clinical outcome at 1 year [11]. In particular, the recurrence rate was 47% with an average CF between 10 and 20 g, and 20% with an average CF > 20 g during ablation [9]. The success rate appears also to be related to the force time integral (FTI), calculated as CF multiplied by time. In the TOCCATA study experience, an increase from 500 to 1000 gs in the FTI shows an increase in the success rate from 25 to 69%, respectively ($p < 0.03$) [10]. In the EFFICAS I study, the segments ablated with minimum FTI of 400 gs had a 95% success isolation rate, which was much higher than those ablated with a lower minimum FTI, whose percentage fell to 79% ($p < 0.001$) [9].

Moreover, further studies have shown that continuity of lesions and ablation catheter stability increase the success rate [12–15]. It is theoretically possible to obtain higher values of FTI using a lower contact for a long time; nevertheless, FTI does not consider power delivery [12]. Therefore, a special lesion index (LSI), associated with the use of Tacticath catheter line, could be used as a single dimensionless index combining three different parameters (CF, ablation time, and amount of energy delivered) as described by the formula

$$\mathrm{LSI}(F,I,t) = k_1 * \left(f_2\left(1-e^{-\frac{F}{f_1}}\right) + f_0\right) * i_2\left(1-e^{-\left(\frac{I}{i_1}\right)^2}\right) * \left((1-k_0) + k_0\frac{1-e^{-\frac{t}{\tau}}}{1-e^{-\frac{60}{\tau}}}\right)$$

where f_0, f_1, and f_2 are force parameter coefficients, i_1 and i_2 are electrical current coefficients, k_0 is a diffusive heating coefficient, k_1 is a rescaling coefficient, and τ is a characteristic time value. The equation is a separable variable function of contact force F, electrical current I, and duration t of ablation [16].

Validated and recommended LSI values in humans are not yet available in literature. In subgroup analysis of both EFFICAS II [12] and TOCCASTAR [17] studies, the authors showed preliminary LSI data for a higher AF freedom rate. Recently, De Mattia et al. [18] applied these LSI values to guide ablation procedures, thus showing an improved clinical outcome vs retrospective data obtained using catheters without contact force sensor.

Aims of this study are the retrospective evaluation of LSI minimum mean value necessary to reach complete PV isolation during trans-catheter ablation and its correlation with AF recurrences at 12 months; the analysis of the correlation and combination of LSI and FTI parameter values; the analysis of global procedural time, radiofrequency (RF) ablation time, rate, and type of procedural and post-discharge complications.

2 Methods

2.1 Patient population

This is a single-center retrospective study with a population of 37 patients who underwent catheter ablation of AF with a three-dimensional (3D) electro-anatomical mapping system. Institutional Review Board approved the study. All patients underwent ablation procedure with Tacticath™ Quartz consecutively between October 2014 and February 2016. No patient had history of a previous AF catheter ablation. Inclusion criteria were (1) patient ≥ 18 years; (2) drug-refractory AF (having failed at least one antiarrhythmic drug), including early persistent cases; and (3) first-time AF ablation. Exclusion criteria were (1) not fulfilling all inclusion criteria; (2) previous AF/AT/AF ablation, atrial surgery or placement of a left atrial appendage closure device, interatrial baffle, or patch; (3) significant structural heart disease, including congenital heart disease (but not patent foramen ovale); (4) moderate to severe mitral valve disease (stenosis and/or regurgitation); (5) hypertrophic or restrictive cardiomyopathy; (6) high-risk conditions of causing cardiomyopathy (including known amyloidosis or alcohol abuse); and (7) uncontrolled heart failure or NYHA functional class IV or uncontrolled ischemic heart disease.

Noninvasive investigations performed in all patients were 12-lead electrocardiogram (ECG); transthoracic echocardiography assessment of left atrial volume, left ventricular function, and valvular incompetence; and trans-esophageal echocardiography to exclude left atrium (LA) appendage thrombus.

2.2 Mapping and ablation procedure

Patients were studied under deep remifentanyl sedation with spontaneous breathing. A temperature probe in the esophagus (SensiTherm™, FIAB, Italy or S-Cath™, Circa Scientific, CO, USA) at the level of the left atrium was used to tag the esophageal location and provide intra-esophageal temperature feedback during the procedure.

A standard decapolar electrode catheter was placed in the coronary sinus. Dual trans-septal puncture was then performed.

Unfractionated heparin bolus was administered immediately before the trans-septal puncture and a subsequent 1000-U/h rate infusion was then used to maintain an activated coagulation time of ≥ 300 s.

A 7F uni-directional irrigated tip sensor force ablation catheter, Tacticath™ Quartz (Abbott, MN, USA), was used to access the LA via the trans-septal puncture site using a deflectable sheath (Agilis™ NxT, Abbott, MN, USA). LA 3D reconstruction was obtained with a circular mapping catheter (Inquiry™ AFocus II™, Abbott, MN, USA) using an electro-anatomical mapping system (EnSite™ Velocity™; Abbott, MN, USA).

Radiofrequency ablation was performed for at least 30 s at each site before the catheter tip was moved to a new adjacent site. The abatement of local signals was used as target of each lesion. RF power was set at 30–40 W with a maximum temperature of 42 °C. Irrigation was performed using saline infusion at a rate of 20 ml/min.

In all patients, a minimum CF target value of 10 g was obtained in each vein. Single vein, segmental circumferential, and consecutive lesions were performed. The values for CF, FTI, and LSI were recorded for each RF pulse and the average value for each index per vein was then calculated.

2.3 Procedural endpoint

The procedural endpoint was electrical PV disconnection. Stimulation from coronary sinus catheter and circular mapping catheter, respectively, allows to check left atrium-PV entrance and exit block, thus proving PV disconnection. In order to evaluate acute pulmonary vein reconnections, adenosine was administrated according to operator's discretion. If sinus rhythm was not achieved during RF delivery in patients with AF, an external electrical cardioversion was performed at the end of PV disconnection and then PV isolation was checked in sinus rhythm.

In patients with clinically documented isthmus–dependent right atrial flutter, ablation of the right atrial cava-tricuspid isthmus was also performed.

2.4 Follow-up

After the blanking period (90 days), patient follow-up was conducted in the outpatient clinic department at 3, 6, and 12 months. According to the latest guidelines for atrial fibrillation ablation, arrhythmia recurrences were defined as episodes of AF/AFL/AT lasting >30 s [15, 19].

A standard 12-lead ECG and a 24-h Holter recording were obtained from all patients at each visit. Clinical events occurring during the follow-up were carefully documented and analyzed.

2.5 Statistical analysis

All data are reported as mean ± standard deviation or percentages. Assuming that population data had a normal distribution (as calculated by means of a Kolmogorov-Smirnov test), we carried out statistical comparisons by applying the two-sample unequal-variance Student t test, linear correlation, and receiver operator characteristic (ROC) curves by using STATA® software ver. 13.1 (StataCorp LP, TX, USA). The chi-square test, together with Pearson's or Fisher's exact test, was performed on categorical data. A probability (p) value ≤ 0.05 was regarded as statistically significant.

3 Results

A total of 37 patients were included in the study. The mean age of the population studied was 61 ± 9 years and 27 out of 37 (73%) were men. Our final study population was composed of 21 (57%) patients with paroxysmal AF, 16 (43%) patients with early persistent AF; baseline clinical characteristics of patients are reported in Table 1. The population involved in this retrospective analysis was homogeneous both in clinical characteristics and procedural data.

Acute pulmonary vein reconnections were observed in 5% of veins: in detail, 2% of reconnections in LSPVs; 2% in RSPVs, 1% in RIPVs; no acute reconnections were detected in LIPVs.

3.1 Follow-up

Twelve (32%) AF recurrences were documented at 12-month follow-up (Fig. 1).

A significant difference regarding gender and left atrium dimension was recorded comparing AF recurrence and no AF recurrence groups; all the other characteristics were homogenous (Table 2).

3.2 Ablation procedure data

RF time per each vein was similar when comparing AF recurrence patient group with no AF recurrence patient group (Table 3). Total RF time, fluoroscopy time, and procedure time showed no significant differences. Fluoroscopy time was 24 ± 13 min for AF recurrence group vs 25 ± 18 min for no AF recurrence group, $p = 0.44$. Procedure time was 145 ± 39 min vs 146 ± 47 min, $p = 0.50$ respectively.

No patients had serious adverse events defined as phrenic nerve injury, pericardial effusion/tamponade, symptomatic cerebral ischemia, or esophageal injury.

As for FTI values (Table 3), the only significant differences between the two groups were found analyzing RIPV.

Table 1 Baseline characteristics of general population

Population (37 pts)	
Male	27 (73%)
Age (year)	61 ± 9
Height (cm)	172 ± 9
Weight (kg)	81 ± 17
BMI	27 ± 4
Left atrium area (cm^2)	25 ± 8
EF (%)	62 ± 8
AF type	
Paroxysmal	21 (57%)
Early persistent	16 (43%)

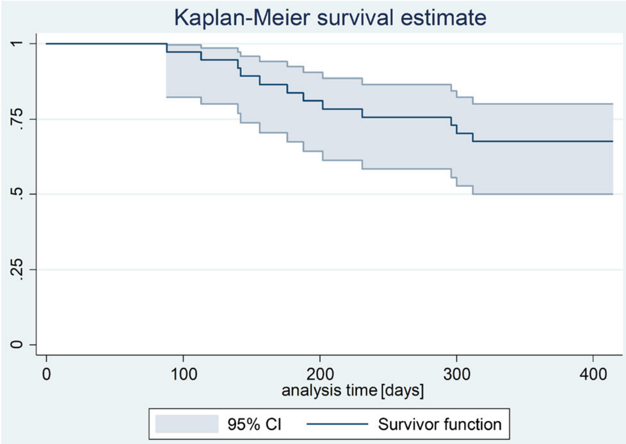

Fig. 1 Kaplan-Meier curve calculated for all enrolled patients: at 365-day follow-up, AF recurrence percentage was 32%

Mean LSI value in patients with and without AF recurrence showed the following results: LSPV values were 5.2 ± 0.7 vs 4.6 ± 0.8, $p = 0.03$; LIPV values were 5.0 ± 0.8 vs 4.5 ± 0.6, $p = 0.04$, respectively; RSPV values were 5.5 ± 0.6 vs 5.1 ± 0.6, $p = 0.05$; and finally RIPV values were 5.5 ± 0.7 vs 4.7 ± 0.8, $p = 0.006$ (Table 3).

LSI and FTI parameters correlate in both groups: LSI and FTI in patients with AF recurrence and patients without recurrences are shown to have a $R^2 = 0.57$ and $R^2 = 0.62$ respectively as shown in Fig. 2a, b.

We defined "cutoff value" as the minimal value able to predict lesion efficacy (no recurrence) at 12-month follow-up. Fig. 3 reports ROC curves for FTI parameter in each vein; the cutoff value is respectively 316 gs in LSPV (sensitivity 36.84%, specificity 88.89%, positive predictive value 53.57%, LR+ 3.32, LR− 0.71), 359 gs in LIPV (sensitivity 75.27%, specificity 55.81%, positive predictive value 69.12%, LR+ 1.70, LR− 0.44), 376 gs for RIPV (sensitivity 65.22%, specificity 90.91%, positive predictive value 73.53%, LR+ 7.17, LR− 0.38), and 405 gs for RSPV (sensitivity 53.85%, specificity 81.82%, positive predictive value 62.16%, LR+ 2.96, LR− 0.56). Considering all veins, the mean cutoff value in Fig. 4a is 350 gs (sensitivity 75.27%, specificity 55.81%, positive predictive value 69.12%, LR+ 1.70, LR− 0.44).

In Fig. 5, ROC curves for LSI parameter in each vein are displayed; the predictive cutoff value is respectively 5.1 for LSPV (sensitivity 56.00%, specificity 75.00%, positive predictive value 62.16%, LR+ 2.24, LR− 0.59) and 5.2 for LIPV (sensitivity 42.11%, specificity 88.89%, positive predictive value 57.14%, LR+ 3.79, LR− 0.65) and 5.1 for RIPV (sensitivity 82.61%, specificity 72.73%, positive predictive value 79.41%, LR+ 3.03, LR− 0.24) and 5.6 for RSPV (sensitivity 42.31%, specificity 81.82%, positive predictive value 54.05%, LR+ 2.33, LR− 0.70). Analyzing all veins, the cutoff value instead appears to be 5.3 (sensitivity 56.99%, specificity 76.74%, positive predictive value 63.24%, LR+ 2.45, LR− 0.56) (Fig. 4b).

No further clinical adverse events were documented during clinical follow-up.

Table 2 Baseline characteristics of the two groups

	AF recurrence [pts = 12]	No AF recurrence [pts = 25]	*p* value
Male	10 (83%)	17 (68%)	0.01
Age (year)	61 ± 8	62 ± 10	0.78
Height (cm)	175 ± 9	171 ± 9	0.24
Weight (kg)	86 ± 20	79 ± 15	0.33
BMI	28 ± 4	27 ± 4	0.59
Left atrium area (cm^2)	22 ± 4	27 ± 8	0.02
EF (%)	62 ± 6	62 ± 9	0.89

Table 3 RF time, FTI, and LSI between AF recurrence and not AF recurrence groups. *p* value demonstrates that RF time was similar for both groups. FTI data show significant differences between the two groups only for RIPV. LSI values show significant differences for each pulmonary vein type and higher values were reached in patients without AF recurrence

RF time (s)	No recurrence	AF recurrence	*p* value
LSPV	368 ± 165	344 ± 118	0.68
LIPV	328 ± 166	300 ± 171	0.72
RSPV	488 ± 223	331 ± 167	0.04
RIPV	420 ± 138	445 ± 259	0.79
FTI (gs)	No recurrence	AF recurrence	*p* value
LSPV	329 ± 117	256 ± 86	0.05
LIPV	318 ± 148	251 ± 109	0.11
RSPV	384 ± 122	319 ± 102	0.07
RIPV	394 ± 123	253 ± 128	< 0.01
LSI	No recurrence	AF recurrence	*p* value
LSPV	5.2 ± 0.7	4.6 ± 0.8	0.03
LIPV	5.0 ± 0.8	4.5 ± 0.6	0.04
RSPV	5.5 ± 0.6	5.1 ± 0.6	0.05
RIPV	5.5 ± 0.7	4.7 ± 0.8	< 0.01

4 Discussion

The present study shows the following key findings: (1) mean LSI value in each vein is always significantly higher in patients without AF recurrence; (2) mean FTI value is not significantly different between the two groups, but in patients with AF recurrence these values are much lower than those recommended by the

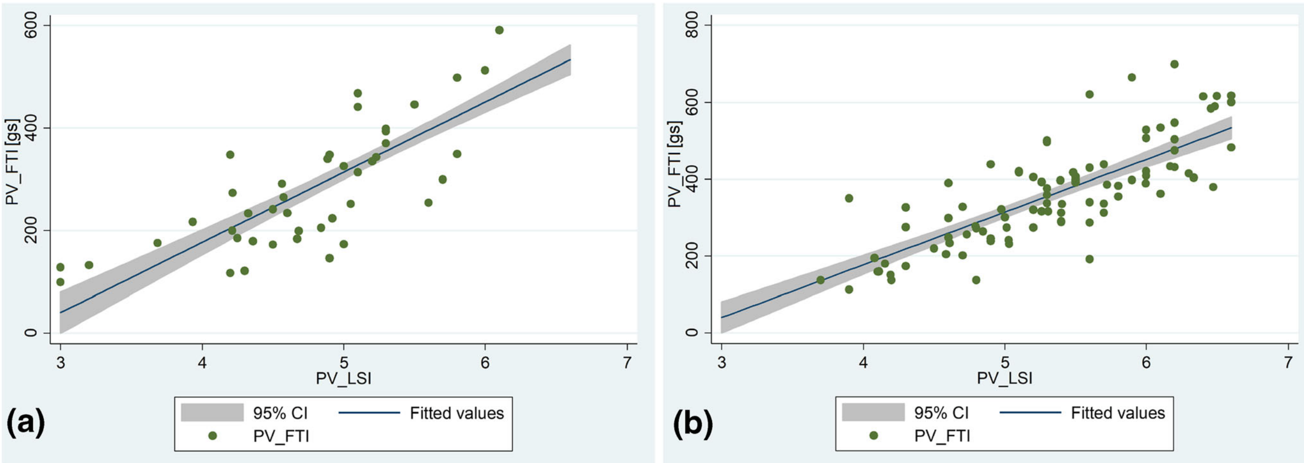

Fig. 2 **a** Correlation between FTI and LSI in AF recurrence group. $R^2 = 0.57$. **b** Correlation between FTI and LSI in no AF recurrence group. $R^2 = 0.62$

EFFICAS II study [12]; (3) LSI and FTI parameters in both analyzed groups appear to be barely correlated; (4) according to our data, mean LSI cutoff value associated with 1-year freedom from AF is 5.3.

LSI is a parameter introduced with Tacticath™ Quartz ablation catheter, which includes information of CF, time, and delivered RF power and can be visualized in real time during RF ablation. This index is predictive

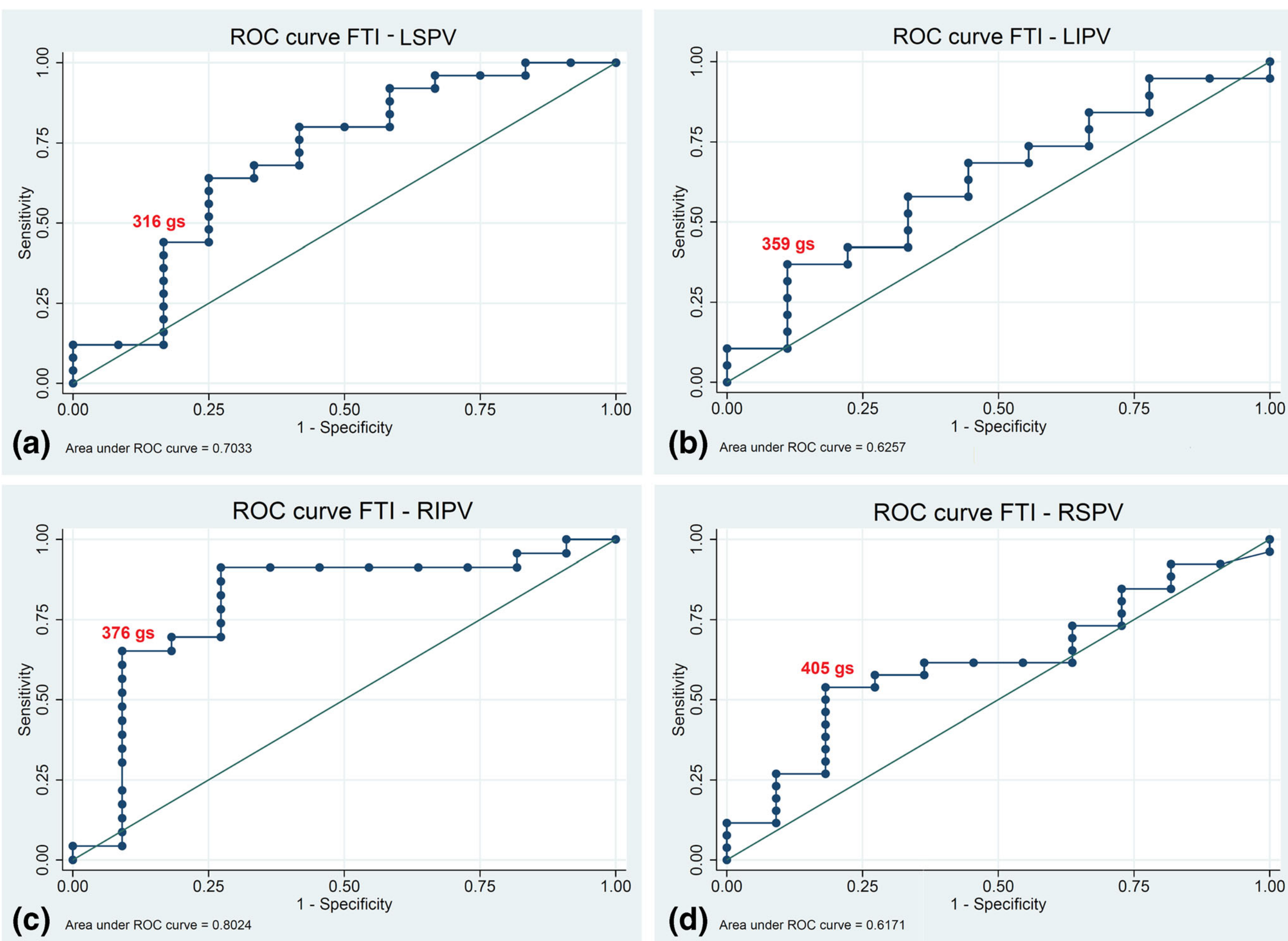

Fig. 3 No AF recurrence group. **a** FTI ROC curve for LSPV—the value that underpins the maximum area is 316 g. **b** FTI ROC curve for LIPV—the value that underpins the maximum area is 359 g. **c** FTI ROC curve for RIPV—the value that underpins the maximum area is 376 g. **d** FTI ROC curve for RSPV—the value that underpins the maximum area is 405 g

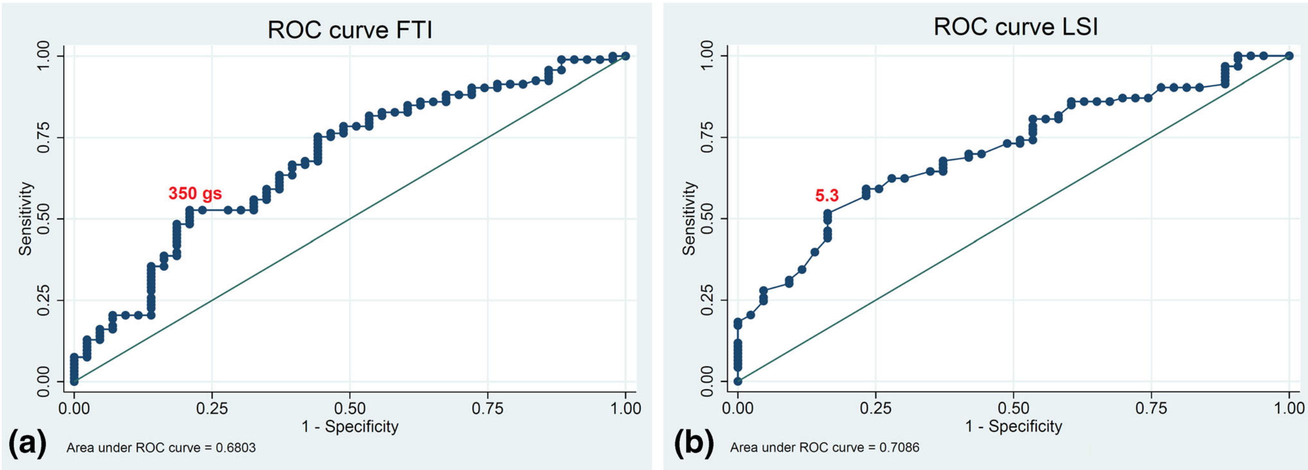

Fig. 4 **a** FTI ROC curve considering all the veins in no AF recurrence group—the value that underpins the maximum area is 350 g. **b** LSI ROC curve considering all the veins in no AF recurrence group—the value that underpins the maximum area is 5.3

of lesion dimension and is useful for predictability of a transmural lesion allowing a successful long-lasting PV isolation.

Due to retrospective nature of our study, the mean value of FTI and LSI has been evaluated in each vein, regardless of specific anatomical sites of ablation.

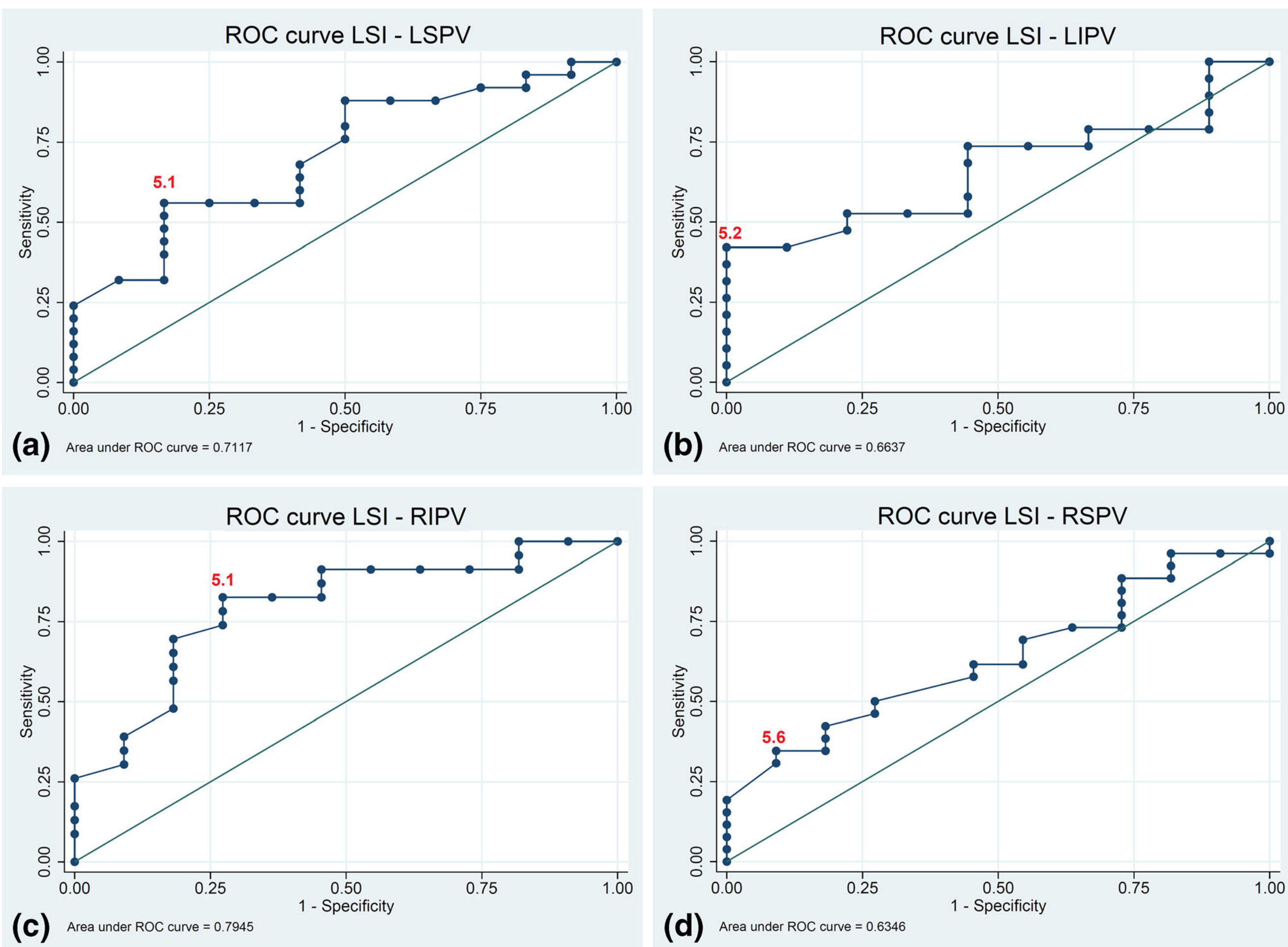

Fig. 5 No AF recurrence group. **a** LSI ROC curve for LSPV—the value that underpins the maximum area is 5.1. **b** LSI ROC curve for LIPV—the value that underpins the maximum area is 5.2. **c** LSI ROC curve for RIPV—the value that underpins the maximum area is 5.1. **d** LSI ROC curve for RSPV—the value that underpins the maximum area is 5.6

Our FTI data showed that the 400 gs value suggested by previous study [9] was not reached in all our patients, because the only targets we used during the ablation procedure were the minimum CF of 10 g and the complete elimination of PV signals.

In patients with AF recurrence, the mean FTI value reached in each vein was lower than the one observed in no AF recurrences. LSI mean values considered in each vein were significantly higher in the group without AF recurrence compared to the group with AF recurrence.

Our results showed that a larger LA size was significantly associated with no AF recurrence. This correlation could be a consequence of the small sample size of the present study. On the other hand, in our study, we performed antral lesion reaching higher LSI values in no AF recurrence patients, even in larger LA. It might suggest that the LA area does not play a critical role in affecting the recurrence rate in our population; in contrast, long-lasting PVI is a crucial aspect. However, further data are necessary to confirm our hypothesis.

Of note, analyzing the data collected with ROC curves: 5.1 for LSPV and 5.2 for LIPV and 5.6 for RSPV and 5.1 for RIPV, we found LSI cutoff values to be predictable for a successful pulmonary vein isolation at 1-year follow-up. Moreover, analyzing all the veins, the cutoff value appears to be 5.3, which is comparable with those reported in literature [12, 17, 18].

4.1 Study limitation

We are well aware that this is a single-center, non-randomized, and retrospective study with a limited number of patients.

Due to the retrospective nature of the present study, standard 12-lead ECG and 24-h Holter were used to evaluate arrhythmia events.

We fully agree that the inter-lesion distance is helpful in creating consecutive lesions avoiding potential gaps, which could cause PV reconnections. Unfortunately, the Velocity mapping system used in our study was not provided with a dedicate software (AutoMark™, Abbott, MN, USA) able to allow automatic measurement of the inter-lesion distance.

We focused on mean FTI and LSI values calculated on the RF delivered to each vein. The evaluation of LSI cutoff values, considering the contact force and the delivered power, in different anatomical positions along each ostium could be an interesting topic for a future prospective study with a wider population.

5 Conclusions

Our retrospective analysis shows that LSI might be considered a satisfactory predictive index for long-lasting PV isolation in AF-treated patient. Our findings suggest a LSI mean value higher than 5 to achieve a successful freedom from AF rate at 1-year follow-up. LSI mean values could be used as guiding ablation target for a subsequent prospective study.

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Compliance with ethical standards

Conflict of interest Elena Romanelli is employee of Abbott, Sesto San Giovanni, Italy. Salvatore Pala received consulting fees from Abbott Medical Italy. Dr. Antonio Dello Russo received consulting fees/honoraria from Biosense Webster. Dr. Gaetano Fassini, Dr. Massimo Moltrasio, and Dr. Fabrizio Tundo received consulting fees/honoraria from Medtronic. Prof. Claudio Tondo received consulting fees/honoraria from Abbott, Medtronic, Boston Scientific, and Biosense Webster. He serves as member of EU Medtronic Advisory Board and Boston Scientific Advisory Board. The other authors declare no relationships with industry.

Ethical approval The study was approved by the Institutional Review Board of Centro Cardiologico Monzino IRCCS.

Informed consent Patients were provided informed consent.

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