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Postprocedural LGE-CMR comparison of laser and radiofrequency ablation lesions after pulmonary vein isolation

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Abstract

Introduction: The purpose of this study was to compare the anatomical characteristics of scar formation achieved by visual-guided laser balloon (Laser) and radiofrequency (RF) pulmonary vein isolation (PVI), using late-gadolinium-enhanced cardiac magnetic resonance imaging (LGE-CMR).

Methods and results: We included 17 patients with paroxysmal or early persistent drug resistant AF who underwent Laser ablation; 2 were excluded due to procedure-related complications. The sample was matched with a historical group of 15 patients who underwent PVI using RF. LGE-CMR sequences were acquired before and 3 months post-PVI. Ablation gaps were defined as pulmonary vein (PV) perimeter sections showing no gadolinium enhancement. The number of ablation gaps was lower in Laser versus RF ablations (median 7 vs. 14, P = 0.015). Complete anatomical PVI (circumferential scar around PV, without gaps) was more frequently achieved with Laser than with RF (39% vs. 19% of PVs, P = 0.025). Fewer gaps were present at the superior and anterior left PV and posterior right PV antral regions in the Laser group, compared to RF. Scar extension into the PVs was similar in both groups, although RF produced more extensive ablation scar toward the LA body. AF recurrences at 1 year were similar in both groups (Laser 36% vs. RF 27%, P = 1.00).

Conclusions: Compared to RF, Laser ablation achieved more complete anatomical PVI, with less LA scar extension. However, AF recurrence appears to be similar after Laser compared to RF ablation. Further studies are needed to assess whether the anatomical advantages of Laser ablation translate into clinical benefit in patients with AF.

KEYWORDS

atrial fibrillation, cardiac magnetic resonance imaging, catheter ablation, laser, late gadolinium enhancement, pulmonary vein isolation, scar

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1 | INTRODUCTION

Pulmonary vein isolation (PVI) is the most common procedure to treat atrial fibrillation (AF) resistant to pharmacological treatment. The traditional nonsurgical PVI technique, point-by-point radiofrequency (RF) ablation, has limited efficacy and potential complications. 1,2 A major reason for its limited efficacy may be the high reconnection rate of pulmonary veins (PVs) to the atrial myocardium, due to the difficulty of achieving linear lesions with a point-by-point technique^{3,4} and of achieving transmural lesions, especially at certain anatomical sites around the PVs. In recent years, new technologies have been designed to achieve circumferential PVI.5,6 The efficacy of the first of these, cryoballoon ablation, appears similar to RF ablation in preventing AF recurrence, probably because of the inability to achieve uniform contact and energy delivery around the PV antrum. More recently, visualguided Laser balloon (Laser) ablation has been developed, with the added advantage of direct visualization of the PV antrum (through a built-in endoscope) and directional delivery of laser energy.^{5,6} Initial studies provided encouraging results on the efficacy of this technology in achieving durable PVI.7-16 which may result from uniform and durable lesions around the PV antrum.¹⁷ However, few studies have compared the anatomical characteristics of lesions performed using Laser balloons to standard RF ablation lesions, and these provided conflicting results.

The objective of the present study was to evaluate the anatomical characteristics of ablation scar formation by Laser versus RF, as visualized by late-gadolinium-enhanced cardiac magnetic resonance imaging (LGE-CMR).

2 | METHODS

2.1 | Patient characteristics

Seventeen eligible patients with paroxysmal or early persistent drugresistant AF and indication for PVI were prospectively enrolled between May 2014 and July 2016. All patients underwent first-time PVI. We excluded patients aged <18 years and those with contraindication for 3-T cardiac magnetic resonance (advanced renal failure, morbid obesity, pacemaker/implantable cardioverter-defibrillator, prior adverse events to magnetic contrast agent, claustrophobia, or pregnancy). To form a control group, a series of patients who underwent RF PVI were clinically matched (sex, age, LA diameter, and AF type) with the included patients with Laser PVI. At 3 months postablation, we collected LGE-CMR data on the presence of gaps, lesion extension, and location, along with procedure and fluoroscopy times and AF recurrence rate after ablation.

The study protocol was approved by the hospital's ethics committee, and participants signed written informed consent.

2.2 | LGE-CMR acquisition

LGE-CMR was performed twice, before and 3 months after ablation, in all patients. The acquisition protocol has been previously

reported. ^{18,19} Briefly, images were acquired 20 minutes after an intravenous bolus injection of 0.2 mmol/kg gadobutrol (Gadovist, BayerShering) in a 3-Tesla CMR scanner (Magnetom Trio, Siemens Healthcare), using a ECG-gated sequence with respiratory navigator. Inversion time was set to suppress the healthy myocardium.

2.3 | Analysis of the LGE-CMR

The left atrium of the patients was analyzed using the image post-processing software ADAS-AF (Galgo Medical S.L.). To perform the myocardium delineation, an experienced operator drew the mid-wall of the atria at several short axis slices of the LGE-CMR, and the software automatically interpolated the delineation for the rest of the slices. The software then generated a 3D model of the atria from the slice-by-slice segmentation. The expert then manually checked the 3D reconstruction and adjusted the wall position in the LGE-CMR volume if necessary.

2.4 | Tissue characterization

Once the 3D model of the atrium was properly adjusted, ADAS-AF mapped the fibrosis of the LGE-CMR acquisition (the voxel intensity) to the 3D surface mesh representing the atrial wall and the ostia of the PVs. To do so, the software projects the intensity value of the LGE-CMR to each vortex of the 3D model, and displays this information as a color map superimposed on the 3D volume. The ADAS-AF color map uses purple for healthy tissue, red for dense fibrotic areas, and blue, green, and yellow for intermediate fibrotic areas (ranging from less contrast in the LGE-CMR, related to more diffused fibrosis, to greater intensity, related to denser fibrosis). The operator can then see a 3D map of the contrast enhancement at each point of the atrial wall, which relates to the average fibrosis. The values for healthy or pathological tissue were derived from a population of healthy volunteers. ²⁰ Briefly, CMR values are normalized by the atrial blood-pool average value, computing the IIR index,²¹ and IIR values of 1.20–1.32 are computed as thresholds for border-zone tissue and dense fibrotic tissue, where 1.20 corresponds to the average IIR for the healthy population plus 2 standard deviations, and 1.32 corresponds to 60% of the maximum intensity value of patients who have dense atrial fibrosis due to a previous ablation procedure. Further details about the ADAS-AF software have been published elsewhere. 18-20 An illustrative example of the process of LA scar identification is depicted in Figure 1.

Thus, new LGE-CMR regions of the LA wall with an IIR \geq 1.32 localized around the PV after PVI were defined as ablation-induced scar; LA wall regions at that location displaying normal tissue characteristics (IIR < 1.20) were defined as gaps. The following parameters were measured:

- Percentage of gap (Gap%), defined as the total circumference of the
 PV antrum without fibrosis divided by the total circumference of the
 PV antrum.
- The location of the gaps in relation to the perimeter of the PVs, assessed using a 4-segment model where the antral region of the

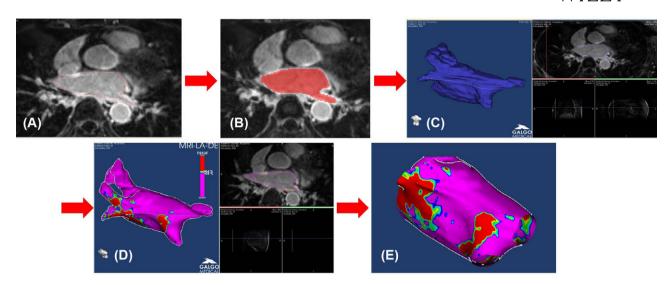


FIGURE 1 The sequence of defining scar areas on late gadolinium enhanced cardiac magnetic resonance imaging (LGE-CMR) using the ADAS-AF program. First, LGE-CMR images were acquired using a standardized protocol and were imported into the ADAS-AF program (A). The left atrial wall was tracked manually at different levels, and the program used those boundaries to define the blood-pool intensity based on voxel intensity (B). Also, using based on the left atrial wall tracking, the program reconstructed a provisional 3D shape of the left atrium (C). The operator checked the accuracy of wall tracking and a final 3D left atrial geometry was created. Then, the software projected the intensity value of the LGE-CMR to each vertex of the 3D model, and displayed this information as a color map (i.e., representing fibrosis) superimposed on the 3D volume (D). Finally, the pulmonary veins, left atrial appendage, and mitral valve were excluded from the model (E) [Color figure can be viewed at wileyonlinelibrary.com]

left and right PVs, respectively, were divided into superior, anterior, inferior, and posterior locations.²²

- Scar area induced by ablation (Scar_{abl}), defined as the difference between the total fibrosis area visualized on the LGE-CMR after the ablation compared with the LGE-CMR before ablation.
- Scar width (Scar_w), defined as Scar_{abl} divided by the total perimeter of the ablated PV.
- The extension of the ablation scar inside the PV (D_{distal}), defined as the distance (in mm) between the PV ostium and the most distal (i.e., PV) border of ablation-induced scar on the postprocedural LGE-CMR, measured and averaged at three sites for each PV (anterior, posterior, and superior [for superior PVs] / inferior [for the inferior PVs] aspect of the vein).
- The extension of the ablation scar into the LA body (D_{prox}), defined as the distance (in mm) between the PV ostium and the most proximal (i.e., toward the LA body) border of ablation-induced scar on the postprocedural LGE-CMR, measured and averaged with D_{distal} . By convention, distances from the PV ostium into the PVs received negative values, while distances from the PV ostium into the LA body received positive values.

2.5 | Ablation procedure

Electrical PVI was the primary intention of catheter ablation in both groups. Procedures were performed under conscious sedation and analgesia. During the catheter procedure, an infusion of heparin was maintained to achieve an activated clotting time >300 seconds.

The LA was accessed via the transseptal route from the right femoral vein to introduce the ablation catheter. A second transseptal

puncture introduced the 8-F sheath used for placement of a multipolar circular catheter into the LA to map signals before and after ablation at the ostial sides of PVs. Complete isolation was verified as a disappearance of bipolar signals. Exit block from the vein was confirmed by pacing through the circular catheter positioned at the PV ostia in all patients. Far-field signals were identified by standard maneuvers.

The characteristics of Laser balloon have been described elsewhere.^{5,6} Briefly, the Laser catheter consists of a compliant balloon filled with deuterium oxide, an endoscope (to visualize the PV ostium and the lesions), and a 980-nm laser diode arc generator (to achieve ablation). The laser energy is directed to the PV antrum in overlapping 30 degrees arcs. The initial ablation covers 270 degrees of the circumference of the PV. The balloon is then rotated to complete the circumferential ablation of the PV.

Based on the specifications of the Laser balloon, ablation power was set to 10 or 12 W for left PVs, to 8.5 W for right PVs, near the esophagus and the phrenic nerve. During Laser ablation of the antrum of the right-sided PVs, phrenic movement was monitored by continuous phrenic nerve stimulation via a right atrial catheter.

RF ablation was performed around the PV antrum, with RF power up to 40 W at the anterior LA wall and up to 30 W for ablation of the posterior LA wall, guided by a 3D electroanatomic mapping system (CARTO, Biosense Webster; or Ensite Velocity or Ensite Precision, St. Jude Medical). All RF ablations were performed with contact force-sensing catheters, and the operator aimed to achieve a minimum pressure of 8 g at all ablation sites before finishing the operation.²³

TABLE 1 Baseline characteristics of the population

	LASER (n = 15)	RF (n = 15)	Total (n = 30)
Age (years) (median, IQR)	58 (52-63)	59 (54-64)	58 (54-63)
Sex (male) (n, %)	11 (73.3%)	11 (73.3%)	22 (73.3%)
LA diameter (mm) (median, IQR)	41 (38-45)	40 (38-46)	41 (38-46)
Paroxysmal AF (n, %)	13 (86.7%)	13 (86.7%)	26 (86.7%)

2.6 | Patient follow-up

Patients were followed up for 12 months. AF recurrence was documented by Holter monitoring and 12-lead ECG at 3, 6, and 12 months and by patient-reported symptoms.

2.7 | Statistical analysis

Continuous data are expressed as median and interquartile range (IQR). Categorical data are expressed with counts and percentages (%). For continuous variables, we used the nonparametric Mann-Whitney U test for comparison between groups. For categorical variables, the Fisher exact test was used to compare proportions between the groups. A P-value of ≤ 0.05 was considered significant. Statistical analysis was performed using SPSS 18.0 (SPSS, Chicago, IL, USA).

3 | RESULTS

From an initial cohort of 17 patients with Laser ablation, 2 were excluded because PVI was not completed due to complications during the procedure (1 atrial perforation without tamponade during the transseptal puncture and 1 phrenic nerve palsy that prevented completion of ablation). Thus, the final study population consisted of 15 patients with Laser ablation and 15 matched controls with RF ablation. The baseline patient characteristics are displayed in Table 1.

Electrical PVI was achieved in all patients at the end of the ablation procedure.

Laser ablation resulted in fewer gaps, compared to RF (Table 2). Complete anatomical PVI (circumferential scar around PV, without gaps) was more frequently achieved in the Laser group, compared with the RF group (39.0% vs. 19.3% of veins, respectively; P = 0.025). However, only 1 patient in each group had circumferential scar without gaps around all PVs (Table 2). The Laser group showed a decreased presence of gaps at the superior and anterior left PV and posterior right PV antral regions, compared to the RF group (Figure 2). Other locations showed a similar presence of gaps between the two technologies. Ablation scar had similar extension inside the PVs in both groups of patients. However, the atrial extension of the ablation scar was larger in the RF group, compared to the Laser group (Table 2). An illustrative example of the apparent differences between Laser and RF ablation is provided in Figure 3.

TABLE 2 LGE-CMR parameters by study group

	LASER (n = 15)	RF (n = 15)	P-value
Scar characteristics			
Total number of gaps (n) (median, IQR)	7.0 (3.5-12.0)	14.0 (8.0-16.5)	0.015
Total gap percentage (%) (median, IQR)	27.0 (13.6-37.9)	51.8 (12.8-59.1)	80.0
Scar area (cm²) (median, IQR)	15.1 (9.8-28.3)	16.4 (9.8-27.0)	0.89
Scar width (mm) (median, IQR)	11.9 (8.4-18.8)	18.0 (14.0-26.3)	0.027
Patients with continuous scar around left-side veins (n, %)	5 (33.3%)	1 (6.7%)	0.17
Patients with continuous scar around right-side veins (n, %)	1 (6.7%)	3 (20.0%)	0.60
Patients with continuous scar around all veins (n, %)	1 (3.3%)	1 (3.3%)	1.00
Scar extension inside pulmonary vein (D _{distal})			
- Left superior pulmonary vein (mm) (median, IQR)	-4.5 (-6.4 to -2.7)	-3.3 (-6.5 to 3.3)	0.07
- Left inferior pulmonary vein (mm) (median, IQR)	-5.2 (-7.4 to -3.7)	-5.2 (-9.2 to -2.3)	0.34
- Right superior pulmonary vein (mm) (median, IQR)	-2.0 (-4.2 to -0.2)	-2.2 (-4.7 to 1.0)	0.36
- Right inferior pulmonary vein (mm) (median, IQR)	-0.9 (-5.3 to 0.5)	0.0 (-2.6 to 3.9)	0.10
Scar extension inside the left atrial body (D _{proximal})			
- Left superior pulmonary vein (mm) (median, IQR)	2.8 (0.0-5.9)	8.1 (4.2-10.1)	0.003
- Left inferior pulmonary vein (mm) (median, IQR)	4.4 (2.7-5.4)	7.0 (4.0-10.2)	0.008
- Right superior pulmonary vein (mm) (median, IQR)	3.1 (0.5-6.6)	8.2 (3.0-10.1)	0.044
- Right inferior pulmonary vein (mm) (median, IQR)	4.6 (1.6-6.5)	9.2 (5.6-11.5)	0.004

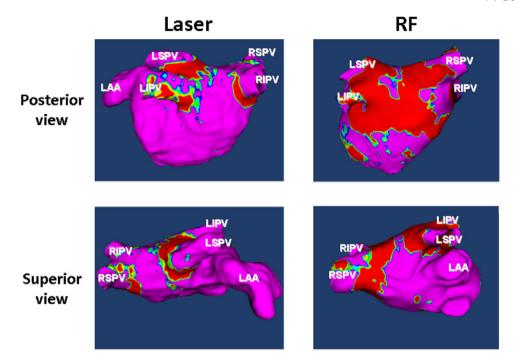


FIGURE 2 3D shell from the late gadolinium enhancement cardiac magnetic resonance imaging analysis using the ADAS-AF software in a Laser (left panels) and radiofrequency (RF, right panels), respectively. Healthy tissue is displayed in magenta, and dense scar tissue in red. Laser achieved narrower and more localized PV ostial lesions compared with RF [Color figure can be viewed at wileyonlinelibrary.com]

Procedure time was longer in Laser compared with RF ablations (median, IQR: 190 [145–210] minutes vs. 136 [120–142] minutes; P=0.002), but fluoroscopy times were similar in both groups (median, IQR: 25.1 [19.8–27.5] minutes vs. 23.6 [10.0–29.3] minutes, P=0.23). AF recurrences at 6 months (Laser 4/15 (27%) vs. RF 3/15 (20%), P=1.00), and 12 months (Laser 5/14 (36%) vs. RF 4/14 (27%); P=1.00) were similar in both groups. The length of gaps was numerically higher in patients with recurrences versus patients without recurrences (65 \pm 39 mm vs. 58 \pm 48 mm, P=0.11).

4 | DISCUSSION

This study provides details on the anatomical differences of scar characteristics achieved using Laser versus RF techniques in patients undergoing AF ablation procedures. Our data suggest that Laser provides more complete anatomical PVI when compared with RF—especially at the anterior aspect of the left PVs and posterior aspect of the right PVs where the contact force achieved by the RF catheters is weaker.^{22,23} This finding was achieved with less extension of scar into the LA body, and similar extension inside the PVs, compared to RF lesions. However, despite these anatomical advantages, the rate of AF recurrence appeared to be similar in both groups.

Although RF ablation is widely used, it has limited efficacy in achieving durable PVI. This may be related to difficulties in obtaining linear lesions using a point-by-point ablation technique and in achieving lesion transmurality.^{22,23} In previous work, we showed a greater presence of LGE-MRI lesion gaps at regions where the contact force achieved with the SmartTouch ablation catheter is weaker:

the antral regions of anterior left PVs ("ridge") and posterior right PVs.²³ Surgical-based techniques can achieve durable, transmural, and complete PVI and prevent AF recurrence more efficiently than catheter-based strategies; however, surgery is highly invasive and prone to major complications.²⁴ Furthermore, extensive ablation of the atrial substrate has no proven advantage, compared with PVI alone, in patients with both paroxysmal and persistent AF.²⁵ Indeed, some data suggest that extensive creation of scar by ablation is associated with development of stiff left atrial syndrome and pulmonary hypertension in a small but significant minority of patients, 26 which is irreversible. Thus, methods are needed to achieve complete PVI with no gaps of transmural lesions, and also with minimal collateral scar formation. We have recently shown the importance of achieving durable anatomical PVI without gaps in the ablation-induced fibrosis around the PVs, because the length of the gaps correlates with the AF recurrence rate after ablation.²⁷ In theory, the ability of visual-guided Laser balloon technology to directly visualize the PV ostia and direct the ablation energy toward visible sites offers an advantage.

Two small prior studies have evaluated the anatomical characteristics of Laser lesions, compared with other technologies. Perrota et al. 28 compared the acute antral lesions performed using Laser (20 patients) to cryoballoon (20 patients), as assessed using electroanatomical voltage maps. They found that the isolated antral surface area (contiguous area of low voltage <0.5 mV) was smaller in Laser procedures compared with cryoablation (42 \pm 15 cm 2 vs. 57 \pm 14 cm 2 , P = 0.002). However, the durability (as defined by voltage mapping) of these acute lesions was not assessed. In a study that was limited by the very small number of patients included, Khurram et al. compared the baseline to

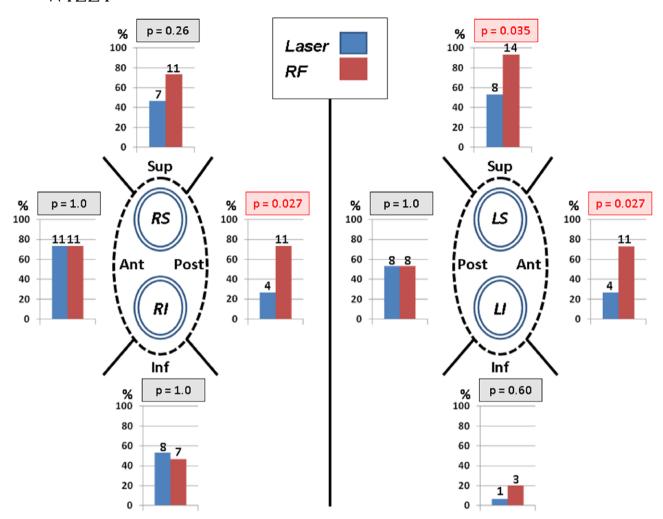


FIGURE 3 Presence of ablation gaps according to pulmonary vein antral locations (superior, inferior, anterior, posterior) (right veins – left panel; left veins – right panel) in patients undergoing Laser (blue bars) versus radiofrequency (RF) ablation (red bars) [Color figure can be viewed at wiley-onlinelibrary.com]

postprocedure change in LA scar burden following Laser (n = 5), RF (n = 5), and cryoablation (n = 7), using LGE-CMR.²⁹ In their study, lategadolinium enhancement showed no differences in scar area between cryoablation and Laser techniques, compared to RF ablation. However, the absolute values of changes in postablation scar area reported by Khurram et al. are compatible with both the Perrota study and our results (Laser vs. RF $-3.2 \pm 3.0\%$; Cryo vs. RF $+4.5 \pm 3.0\%$; all p = NS). The anatomical completeness of the ablation lines was not assessed by the earlier studies. In this context, our results are important because they show that Laser ablation achieves more defined and less aggressive scarring, with more complete and durable anatomical PVI, compared with RF. Indeed, perfect linear lesion deployment with a pointby-point RF ablation technique is difficult to achieve because it would require perfect geometry assessment and integration within the 3D navigation system, perfect matching between the 3D LA dimensions during the procedure and the time when the LGE-MRI was performed, and perfect gating of both cardiac and respiratory movements during the entire procedure. We believe that this gives a rationale for performing larger clinical studies to better define the role of Laser ablation in patients with AF.

Initial experience with Laser ablation demonstrated an acute electrical PVI success rate close to 100%, which is similar to RF. 12,30 Clinical efficacy of Laser ablation in preventing AF recurrence also appears to be similar to RF 11,16,31 and cryoablation 14,15 in both paroxysmal 9,11,13 and persistent AF. 16,31 However, the PV electrical reconnection rate after Laser ablation appears to be lower 7,8 than that reported for RF ablation. 3 Our results help to explain these findings.

There was no significant difference between the rate of AF recurrence after Laser versus RF ablation in this small study (P = 1.0). The reasons for the apparent discrepancy between the greater *anatomical* efficacy of durable PVI achieved by Laser compared with RF and the similar *clinical* efficacy of the two techniques are not clear, but it may be related to several factors: (1) Most published studies were underpowered to detect differences because of small sample sizes. Indeed, the largest published study included only 68 patients with persistent AF for Laser ablation and 66 for RF ablation, 31 which is much lower compared with studies that compared cryoablation with RF (over 375 patients per group). 32 (2) Most studies included the first patients in whom Laser was performed in that center, so the operator's learning curve may have been a factor. (3) Some studies included

both paroxysmal and persistent AF, 13 but this clinical classification lacks precision. 33 Moreover, the largest study comparing Laser with RF ablation included patients with persistent AF, 32 but in these patients the best ablation strategy is still undefined. (4) Various aspects of PV anatomy and orientation significantly influence the ability of Laser balloon to achieve circumferential PVI. 17 (5) Electrical PV reconnection does still occur after Laser ablation (40% of patients have at least 1 reconnected PV at 105 ± 44 days after the procedure). 8 In our study, even though Laser provided better anatomical PVI compared with RF, LGE-MRI defined gaps were still present in the majority of patients, and only at the left inferior PV antral region were >80% of patients free of gaps (with both techniques).

All balloon ablation techniques are associated with higher risk of right phrenic nerve palsy, compared with RF. This may be explained by the fact that balloon ablation techniques (including Laser) achieve higher transmurality of the lesions at anterior right PVs. ¹¹ Our results fit well with this observation.

5 | LIMITATION OF THE STUDY

We included a small number of patients in our study, which precludes further analysis of the relationship between the anatomical characteristics of scar formation due to ablation and the risk of AF recurrence after the procedure.

LGE-MRI provides a visual pattern of lesion formation. Although there is not a perfect match between LGE-MRI gaps and electrical gaps, previous studies have shown a sufficient correlation to guide redo procedures, ¹⁹ and a correlation of LGE-MRI gaps with recurrences and contact force.²³

We did not take into account the impact of the learning curve on our results. Similarly, we did not assess the impact of various PV orientation and anatomies on our results and on scar formation. These are important considerations for future research.

6 | CONCLUSIONS

Laser ablation achieves more complete anatomical PVI, with less extension of ablation-induced scar into the LA body, compared to RF. However, these anatomical advantages did not translate into lower AF recurrence rate after Laser when compared to RF ablation in this small study. Further studies are necessary to fully characterize the role of this new ablation procedure in treating patients with AF.

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