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ORIGINAL ARTICLE

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Pulsed field ablation technology for pulmonary vein and left atrial posterior wall isolation in patients with persistent atrial fibrillation

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Abstract

Introduction: Limited data exist on pulsed-field ablation (PFA) in patients with persistent atrial fibrillation (PeAF) undergoing left atrial posterior wall isolation (LAPWI).

Methods: The Advanced TecHnologies For SuccEssful AblatioN of AF in Clinical Practice (ATHENA) prospective registry included consecutive patients referred for PeAF catheter ablation at 9 Italian centers, treated with the FARAPULSE^{TM}-PFA system. The primary efficacy and safety study endpoints were the acute LAPWI rate, freedom from arrhythmic recurrences and the incidence of major periprocedural complications. Patients undergoing pulmonary vein isolation (PVI) alone, PWI + LAPWI and redo procedures were compared.

Results: Among 249 patients, 21.7% had long-standing PeAF, 79.5% were male; mean age was 63 ± 9 years. LAPWI was performed in 57.6% of cases, with 15.3% being redo procedures. Median skin-to-skin times (PVI-only 68 [60–90] vs. PVI + LAPWI 70 [59–88] mins) did not differ between groups. 45.8% LAPWI cases were approached with a 3D-mapping system, and 37.3% with intracardiac echocardiography. LAPWI was achieved in all patients by means of PFA alone, in 88.8% cases at first pass. LAPWI was validated either by an Ultrahigh-density mapping system or by recording electrical activity + pacing maneuvers. No major complications occurred, while 2.4% minor complications were detected. During a median follow-up of 273 [191–379] days, 41 patients (16.5%) experienced an arrhythmic recurrence after the 90-day blanking period, with a mean time to recurrence of 223 ± 100 days and no differences among ablation strategies.

Marco Schiavone, Francesco Solimene, and Claudio Tondo are contributed equally to the study.

Clinical Trial Registration: Advanced TecHnologies For SuccEssful AblatioN of AF in Clinical Practice (ATHENA). URL: http://clinicaltrials.gov/ Identifier: NCT05617456.

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Conclusion: LAPWI with PFA demonstrates feasibility, rapidity, and safety in real-world practice, offering a viable alternative for PeAF patients. LAPWI is achievable even with a fluoroscopy-only method and does not significantly extend overall procedural times.

KEYWORDS
atrial fibrillation, electroporation, left atrial posterior wall isolation, pulsed-field ablation

1 | INTRODUCTION

Catheter ablation for atrial fibrillation (AF) is a well-established treatment for preventing AF recurrences.[1] The primary ablation target in both paroxysmal and persistent AF (PeAF) is the complete isolation of pulmonary veins (PVs) by means of linear lesions around their antra, though in PeAF patients more extensive ablation has been often advocated.[1] Left atrial (LA) posterior wall (PW) isolation by means of thermal energy sources (point-by-point radiofrequency ablation or cryoballoon ablation) in addition to PV isolation (PVI) has emerged as a potential strategy for improving persistent AF ablation outcomes, though conflicting results have been reported.[2–6] The different outcomes regarding LAPW isolation (LAPWI) in addition to PVI may partly arise from the absence of a standardized method of PW isolation, which may hinder the effective achievement of consistent electrical isolation.[7,8] Moreover, if the rate of periprocedural complications is overall low, especially when performing PVI-only, atrio-esophageal fistula remains a potentially life-threatening complication of AF ablation procedures, mainly involving LAPWI. If its incidence is traditionally reported to be low (0.02%–0.1%), it is of particular concern due to its high mortality rate, ranging from 50% to 83%.[9] A recent European survey showed that 0.025% procedures were complicated by an atrio-esophageal fistula (mostly using radiofrequency, 0.038%), with an overall mortality of 65.8%.[10]

Pulsed field ablation (PFA) has drawn interest owing to its remarkable capacity to minimize collateral tissue damage while maintaining high efficacy in myocardial ablation, thereby limiting its potential collateral damage to the surrounding tissues and structures, as the esophagus.[4] To date, however, few data are available on a non-thermal PFA approach by means of irreversible cellular electroporation targeting LAPW in PeAF patients.[11–15] Indeed, we sought to explore PFA in PeAF assessing the use of the FARAPULSE™ (Boston Scientific) PFA catheters beyond PVI, extending the lesion set to LAPW ablation.

2 | METHODS

2.1 | Patient population and study design

From July 2022 to May 2023, 249 consecutive patients referred for PeAF ablation and undergoing their ablation procedure with the novel FARAPULSE™ PFA system (Boston Scientific) at nine Italian centers were included in the Advanced TecHnologies For SuccEssful AblatioN of AF in Clinical Practice (ATHENA) project. All patients were followed-up at their own enrolling center, from the time of first ablation to the last follow-up visit. The study complied with the Declaration of Helsinki; the locally appointed ethics committee approved the research protocol, and informed consent was obtained from all patients. In the EU, the use of the FARAPULSE™ (Boston Scientific) ablation system for the treatment of PeAF ablation is outside of the labeled indication as safety and effectiveness have not been established yet.

2.2 | Ablation procedure

All procedures were performed either under deep conscious sedation or under general anesthesia. Periprocedural and intraprocedural anticoagulation was administered in accordance with the latest guidelines.[1] The procedure utilized the new multi-electrode basket-type 12 F over-the-wire PFA catheter (FARAWAVE™, Boston Scientific). The navigation of each spline was achieved through a 13 F steerable sheath (FARADRIVE™, Boston Scientific) and was deployed in the desired shape, advancing it into position at the ostium of each PV and at the antrum of each PV.[16] A standard PFA protocol to reach PVI was applied, as described elsewhere.[17] The ablation endpoint was determined based on electrogram recordings, with the FARAWAVE™ catheter placed sequentially in each PV. In cases of sinus rhythm, pacing from the coronary sinus was performed to distinguish the PV spike from LA far-field electrograms.

2.3 | LAPWI

Once PVI was completed, LAPWI was performed at operator's discretion. To achieve LAPWI, PFA was applied to create continuous lesions adjacent to each other, connecting the floor (between the bottoms of the right and left inferior PVs), the roof (between the tops of the right and left superior PVs) and the inner wall (within the floor and the roof) to complete entire PW isolation. LAPW ablations were performed in a flower configuration only and each application followed the same approach of two cycles per shot. Additional lesions were performed at carina sites, whenever required (Figure 1). After PFA delivery, each step was validated by analyzing electrical

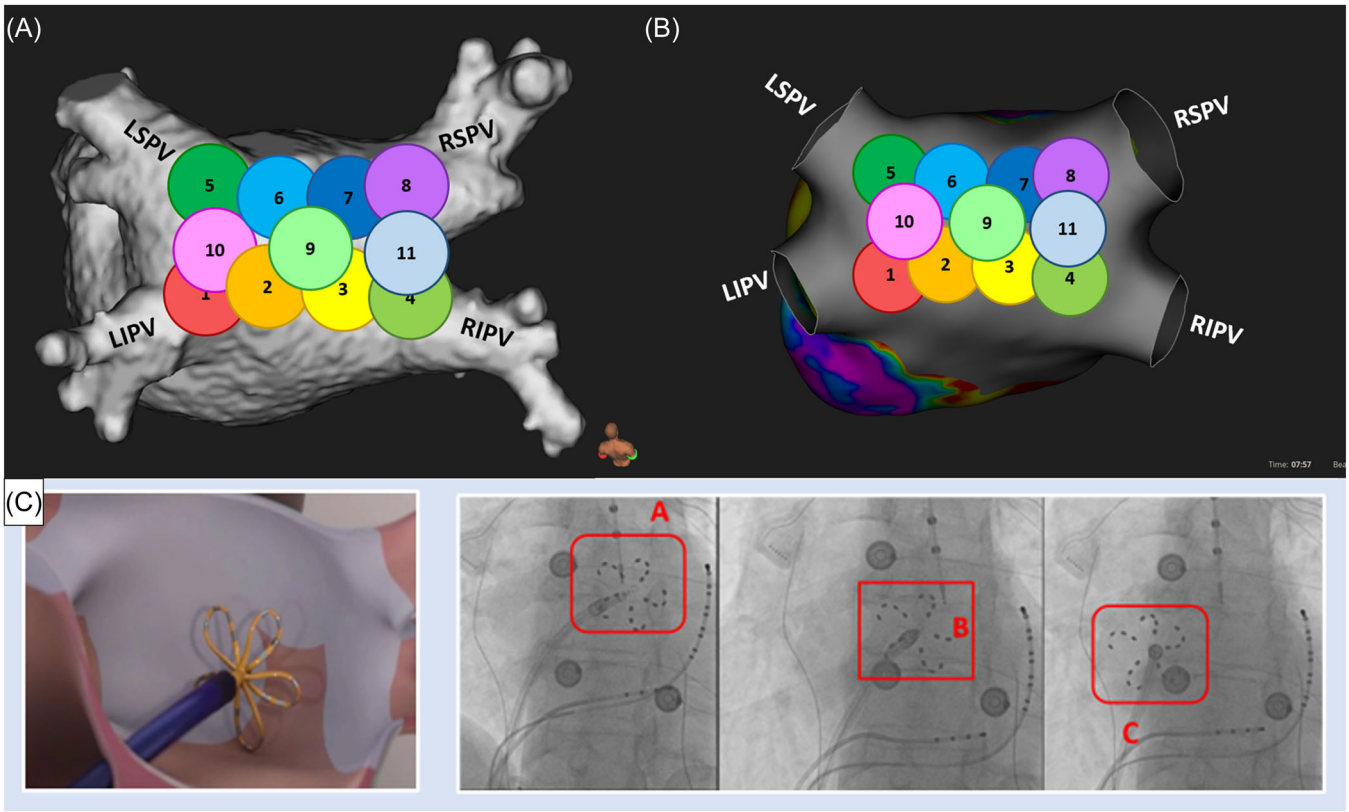

FIGURE 1 Once PVI was completed, LAPW isolation was performed at operator's discretion. To achieve LAPW isolation, PFA was applied to create continuous lesions adjacent to each other, connecting the floor (between the bottoms of the right and left inferior PVs, circles 1–4), the roof (between the tops of the right and left superior PVs, circles 5–8) and the inner wall (within the floor and the roof, circles 10 and 11) to complete entire PW isolation. Additional lesions were performed at carina sites, whenever required (circle 9). (Panel A): CT reconstruction of the left atrium anatomy; (Panel B): 3D-mapping reconstruction of the left atrium; (Panel C): Example of fluoroscopy visualization of LAPW ablation. LAPW, left atrial posterior wall; PFA, pulsed field ablation; PV, pulmonary veins; PW, posterior wall.

signals from the PFA splines. The inability of atrial pacing using high-output (2 ms, 20 mA) energy in the LAPW was verified to demonstrate efferent block. If local conduction persisted, additional ablation was performed in the local area.[18]

2.4 | 3D-mapping analysis

Ultra-high-resolution 3D-mapping was used at operator's discretion by means of the Carto™, NAVx™, or Rhythmia™ system, representing the validation group. Electrograms with voltages above 0.5 mV were considered to indicate healthy and unablated tissue, while electrograms with voltages less than 0.2 mV were deemed to indicate dense scar tissue. Points with voltages between 0.2 and 0.5 mV were defined as indicating damaged but viable tissue.[19,20] Postablation remapping was carried out during coronary sinus pacing, to accurately pinpoint any conduction gaps in the ablation lines. (Figure 2) The LAPW surface was defined as the area between the PV lesions on the PW bordered on the supero-inferior aspect by two lines connecting the most superior and inferior points of the circumferential PV lesions (Supporting Information: Figure 1). To analyze lesion formation and residual gaps, the line around each pair of PVs was divided into 7 distinct sections in accordance with the literature,[18,21] while the roof line, the floor line, and the two longitudinal PW lines were equally divided into three parts, and the PW was divided into nine regions[22] with two additional sections identifying extended LAPW ablation areas and two regions identifying left and right carina (Figure 3A). LAPW bipolar voltage mapping was used if potentials were still recorded in the PW and the earliest activation site was inside the PW far from the ablation line after high-density mapping.

2.5 | Postablation management and follow-up

Regular follow-up assessments involved outpatient clinic visits at 1, 3, 6, and 12 months after the procedure, or whenever complaints arose. These assessments included a comprehensive history review, physical examination, 12-lead electrocardiogram, 24-h or 7-day Holter-ECG monitoring, and screening for any adverse events. At the 3-month mark, the decision to continue anticoagulation was based on the stroke risk, while antiarrhythmic drugs (AAD) discontinuation was left at physicians' discretion. During the first 3 months following the ablation procedure (blanking period), any occurrence of AF/AFL/AT (AF/flutter/tachycardia) was not considered a recurrence. Thereafter, episodes of atrial tachycardia or atrial flutter were also classified as recurrences.

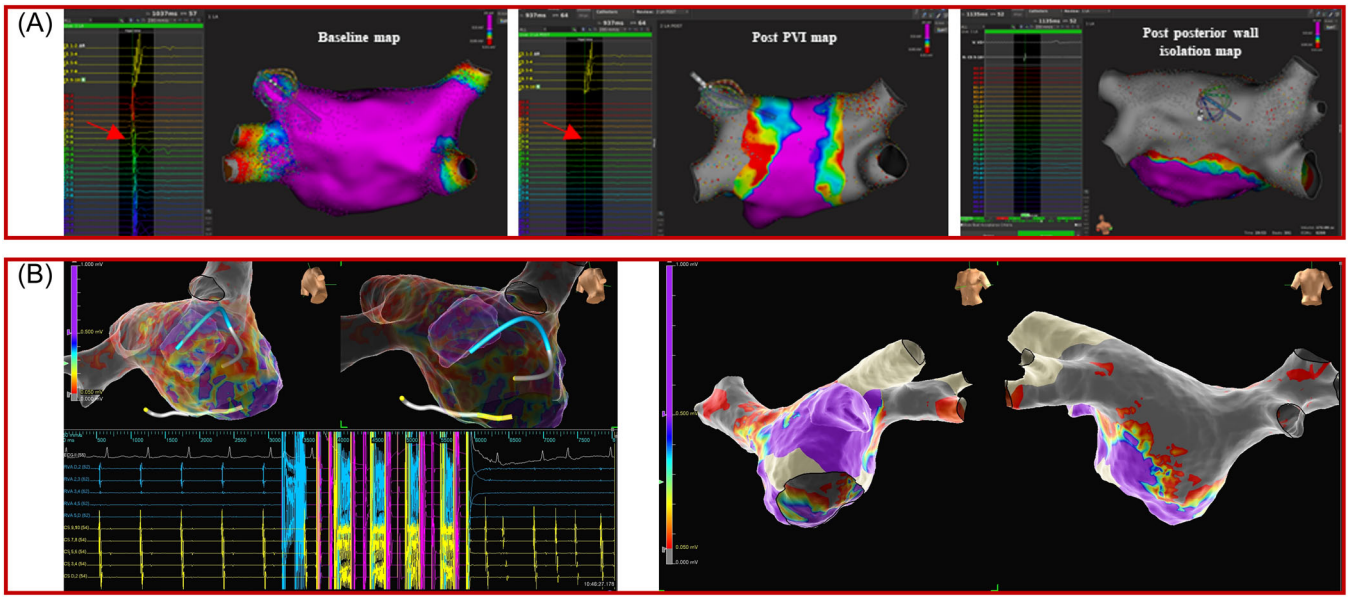

FIGURE 2 Examples of LAPWI validation performed through 3D-mapping in a de novo case (Panel A: Rhythmia™ mapping system) and in a redo case (Panel B: NAVx™ mapping system). Remaping of the LA was carried out during coronary sinus pacing, to accurately pinpoint any conduction gaps in the ablation lines, and additional validation was performed through voltage and activation mapping. LAPWI, left atrial posterior wall isolation.

2.6 | Study cohort and study endpoints

PeAF patients enrolled in this study were divided into three cohorts: (1) patients undergoing a PVI-only procedure; (2) patients undergoing a PVI + LAPWI procedure; (3) redo-AF ablation patients. The primary efficacy endpoint of this study was the rate of acute electrical LAPWI and freedom from arrhythmic recurrences during follow-up. The primary safety endpoint was the rate of major periprocedural complications defined as follows: procedure-related death, stroke, or transient ischemic attack (TIA), pericardial effusion requiring pericardiocentesis or surgery, atrio-esophageal fistula, and cardiac or vascular injury resulting in shock or requiring emergency surgical intervention. According to European Guidelines and US Guidelines for the Diagnosis and Management of AF,[1] persistent AF was defined as AF that is continuous and sustains for >7 days (but <12 month) and requires intervention, while long-standing persistent AF was defined as AF that is continuous for >12 month in duration.

2.7 | Statistical analysis

Descriptive statistics are reported as means ± SD for normally distributed continuous variables, or medians with 25th-to-75th percentiles in the case of skewed distribution. Normality of distribution was tested by means of the nonparametric Kolmogorov–Smirnov test. Differences between mean data were compared by means of a *t*-test for Gaussian variables, and the *F*-test was used to check the hypothesis of equality of variance. The Mann–Whitney nonparametric test was used to compare non-Gaussian variables. Differences in proportions were compared by applying χ^2-analysis or Fisher's exact test, as appropriate. A $p < 0.05$ was considered significant for all tests. All statistical analyses were performed by means of R (R Foundation for Statistical Computing).

3 | RESULTS

3.1 | Study population

The clinical and procedural data of the 249 consecutive patients are reported in Tables 1 and 2. *N* = 54 patients (21.7%) had a history of long-standing PeAF. Most patients were men (*n* = 198, 79.5%) and the mean age was 63 ± 9 years (Table 1). Most procedures were de novo AF ablation (*n* = 211, 84.7%), whereas 38 (15.3%) were repeated AF procedures. Only 28.5% were in sinus rhythm before the index procedure. A 3D-mapping system was used in about one-third of the procedures (*n* = 82, 32.9%), 75 (30.1%) procedures were ICE-guided. The decision regarding whether to perform PVI-only or PVI + LAPWI was primarily based on the clinical characteristics of the patients. These characteristics included the higher number of electrical cardioversions performed in the PVI-only group compared to the PVI + LAPWI group (PVI-only patients who underwent at least 1 electrical cardioversion *n* = 40, 47.6% versus PVI + LAPWI patients who underwent at least 1 electrical cardioversion *n* = 68, 60.4%, *p* = 0.035) and the higher failure rate of AAD strategies in the PVI-only group (PVI-only patients on AADs at baseline *n* = 67, 72% versus PVI + LAPWI patients on AADs at baseline *n* = 71, 60.2%, *p* = .049). Specifically, in the LAPWI group *n* = 54 cases (45.8%) were approached with a 3D-mapping system and 44 (37.3%) with ICE. There was a reduction (consistent over time) when considering the

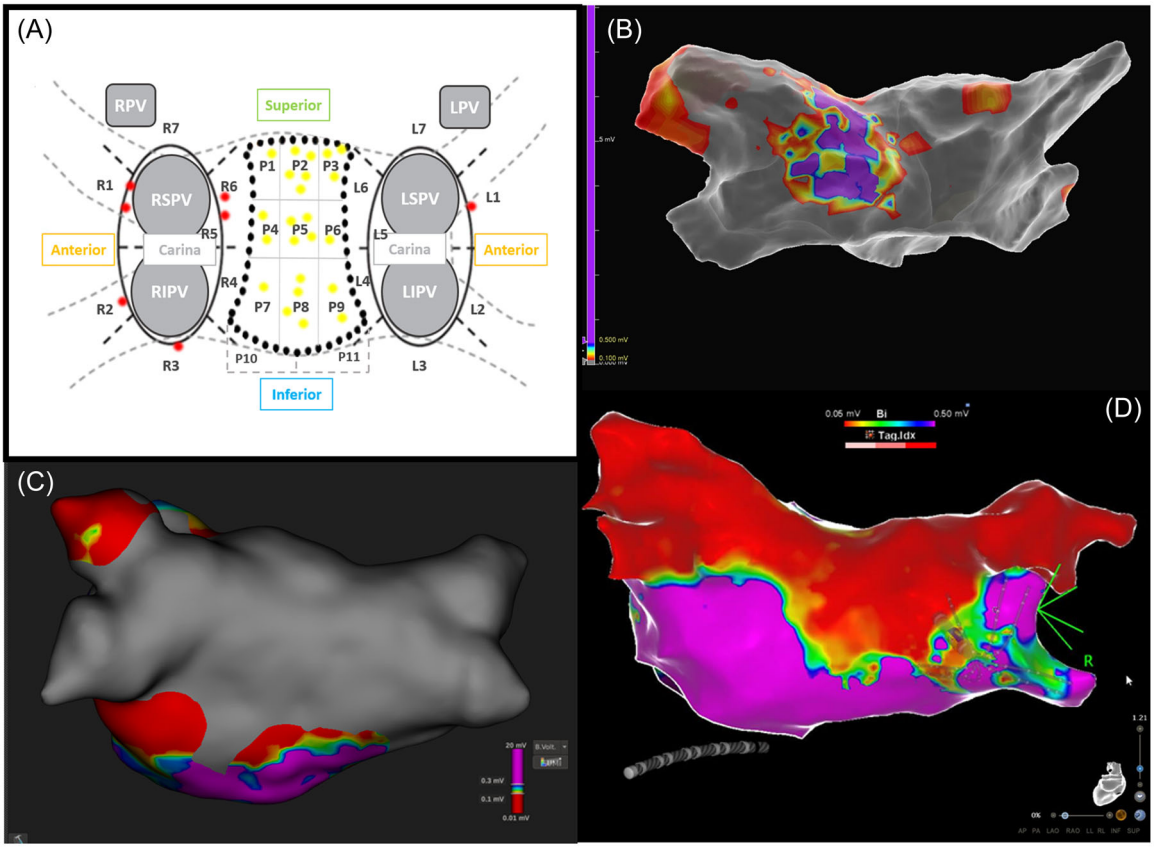

FIGURE 3 To analyze lesion formation and residual gaps, the line around each pair of PVs was divided into seven distinct sections in accordance with the literature, while the roof line, the floor line, and the two longitudinal posterior wall lines were equally divided into three parts, and the PW was divided into nine regions with two additional sections identifying extended PW ablation areas. (Panel A) displays gap locations for PVs with residual PV-conduction following the PFA ablation protocol (red dots) and for LAPW areas with residual atrial activity following the proposed LAPWI workflow (yellow dots). (Panel B) shows example of residual atrial activity in the LAPW region. (Panel C, D) show LAPWI, left atrial posterior wall isolation.

rate of 3D-mapping employment, that we noticed dividing the overall PVI + LAPWI population in four different quarters ($n = 21$ 1st quarter, $n = 16$ 2nd quarter, $n = 10$ 3rd quarter, $n = 7$ 4th quarter). Ablation procedures were more likely to be performed under general anesthesia ($n = 140$, 56.2%), whereas deep sedation was applied less frequently ($n = 109$, 43.8%). Patients' characteristics were similar between de novo PVI only and the de novo PVI plus additional lesion set groups (Table 2).

3.2 | Ablation approach and procedural outcomes

PVI has been achieved in all patients (100%) by means of PFA alone (median number of PFA applications to achieve PVI = 32[23–29]). Thirteen (5.2%) patients exhibited LA anatomical variants (right middle PV $n = 7$ cases, 2.8%—left common trunk $n = 6$, 2.4%). One-hundred ninety-eight (98.0%) PVs were acutely isolated on first pass, as confirmed by both entrance and exit block on subsequent 3D-mapping with the mapping catheter. A total of seven PV gaps were detected through 3D-mapping: four at the RSPV, two at the RIPV and one at the LSPV. Detailed locations of residual PV connections are reported in Figure 3A.

Additional PFA deliveries outside PVs (i.e., LAPW area) were performed in 57.6% ($n = 143$) cases ($n = 141$ PVI + LAPWI $n = 2$ LAPWI only) and required a median of 16 [14-20.5] PFA applications. Complete LAPWI was achieved in all patients and validated through differential pacing or 3D-mapping. In 50 (42.4%) patients undergoing de novo PVI + LAPWI, complete 3D-mapping was performed to validate both PVI and LAPWI. The total mean LAPW ablated area was 20.0 ± 6 cm^2. Among the 50 patients who underwent LAPWI attempt, first-pass roof area (sectors #1 to #3) block was achieved in 44 (88%), first-pass floor area (sectors #7 to #9) block in 43 (86%) and inner-area efferent (sectors #3 to #6) block in 45 (90%) resulting in "first-pass" LAPWI in 40 patients (80%). A total of 23 residual atrial activity gaps were finally detected by means of validation high-output pacing and 3D-mapping: the assessment of single portions of the LAPW through the evaluation of the signal from the PFA splines after each PFA delivery showed an accuracy of 94.9% (437 out 450 sectors), in comparison with the results of subsequent high-output pacing. Pace-mapping block after PFA deliveries was confirmatory with voltage and/or propagation map in all cases (100%). Details are depicted in (Figure 3A) within some examples of residual LAPW

TABLE 1 Clinical characteristics of the study population.

Parameter	Overall population (*n* = 249)	Redo procedures (*n* = 38)	De novo PVI only (*n* = 93)	De novo PVI plus additional lesion set (*n* = 118)	*p* (De novo PVI only vs. De novo additional lesion set)
Age, years	63.4 ± 9	62.4 ± 7	63.4 ± 9	64.4 ± 8	0.1738
Female Gender, *n* (%)	51 (20.5)	3 (7.9)	22 (23.7)	26 (22)	0.8689
Indication for ablation:					
• Persistent AF, *n* (%) • Long-standing persistent AF, *n* (%)	• 195 (78.3) • 54 (21.7)	• 26 (68.4) • 12 (31.6)	• 77 (82.8) • 16 (17.2)	• 92 (78.0) • 26 (22.0)	0.4876
Symptomatic patient, *n* (%)	228 (91.6)	36 (94.7)	82 (88.2)	110 (93.2)	0.2317
History of AT/AFL:					
• AT only, *n* (%) • AFL only, *n* (%) • Both AT and AFL, *n* (%)	13 (5.2) • 3 (1.2) • 9 (3.6) • 1 (0.4)	5 (13.2) • 1 (2.6) • 3 (7.9) • 1 (2.6)	3 (3.2) • 1 (1.1) • 2 (2.2) • 0 (0.0)	5 (4.2) • 1 (0.8) • 4 (3.4) • 0 (0.0)	1
LVEF, %	53.7 ± 10	50.6 ± 11	55.2 ± 10	53.4 ± 9	0.2071
Left atrial volume, mL	42.6 ± 13	47.8 ± 13	42.3 ± 14	42.0 ± 13	0.92
Structural heart disease, *n* (%)	19 (7.6)	3 (7.9)	10 (10.8)	6 (5.1)	0.189
Coronary artery disease, *n* (%)	38 (15.3%)	5 (13.2)	14 (15.1)	19 (16.1)	0.8515
History of heart failure, *n* (%)	15 (6.0)	1 (2.6)	9 (9.7)	5 (4.2)	0.1631
CKD, *n* (%)	6 (2.4)	1 (2.6)	4 (4.3)	1 (0.8)	0.172
COPD, *n* (%)	14 (5.6)	0 (0.0)	3 (3.2)	11 (9.3)	0.0973
Hyperthyroidism, *n* (%)	12 (4.8)	3 (7.9)	0 (0.0)	9 (7.6)	0.0051
Sleep apnea, *n* (%)	10 (4.0)	1 (2.6)	4 (4.3)	5 (4.2)	1
Diabetes, *n* (%)	50 (20.1)	4 (10.5)	16 (17.2)	30 (25.4)	0.1802
Hypertension, *n* (%)	150 (60.1)	22 (57.9)	49 (52.7)	79 (66.9)	0.0467
History of major bleeding, *n* (%)	4 (1.6)	0 (0.0)	2 (2.2)	2 (1.7)	1
Antiarrhythmics, *n* (%)	158 (63.5)	20 (52.6)	67 (72.0)	71 (60.2)	0.0813
Beta-blockers, *n* (%)	168 (67.5)	31 (81.6)	65 (69.9)	72 (61.0)	0.1937

conduction. (Figure 3B–D) After PFA consolidation in those areas, LAPWI was achieved in all cases (100%) by means of PFA alone, with all the additional lesion sets being validated through differential pacing and/or 3D-mapping.

Median skin-to-skin (68 [60–90] vs. 70 [58–88] mins; $p = 0.620$), lab occupancy (100 [70–133] vs. 110 [80–140] mins; $p = 0.093$), and support time did not significantly differ among PVI-only and PVI + LAPWI patients. Total fluoroscopy time and number of PFA deliveries to achieve PVI were comparable among the procedural approaches (17 [14–22] vs. 17 [13–24] mins for fluoroscopy time, $p = 0.741$ and 32 [32–34] vs. 32 [32–40] mins for number of PFA deliveries to achieve PVI, $p = 0.055$, respectively).

No major periprocedural (i.e., stroke/TIA or cardiac tamponade) or anesthesia-related complications were reported. Minor complications (groin hematomas) were reported in six patients (2.4%) after the procedure, no differences were found between PVI only and PVI plus additional lesion set strategies. Conservative treatment and medical therapy were effective in all cases, without prolongation of hospital stay.

During a median follow-up of 273 [191–379] days, 41 patients (16.5%) suffered an AF/AT/AFL recurrence after the 90-day blanking period, with a mean time to recurrence of 223 ± 100 days; 5 recurrences (12.2%) occurred on AADs. We stratified AF recurrence for both AF type ($n = 31$, 15.9% persistent AF patients with recurrences vs $n = 10$, 18.5% long-standing persistent AF patients with recurrences, $p = 0.682$) and ablation strategy ($n = 17$, 18.3% recurrences in the PVI-only group vs 18, 15.3% recurrences in the PVI + LAPWI, $p = 0.580$)—Figure 4. Moreover, $n = 5$ (13.2%) recurrences were found the in the redo group ($p = 0.610$ vs. PVI-only, p = 1.000 vs. PVI + LAPWI).

4 | DISCUSSION

4.1 | Main findings

This is the first study specifically reporting the ablation workflow employed to isolate LAPW with the PFA system, either with only a

TABLE 2 Procedural parameters of the study population.

Parameter	Overall population (*n* = 249)	Redo procedures (*n* = 38)	De novo PVI only (*n* = 93)	De novo PVI plus additional lesion set (*n* = 118)	*p* (De novo PVI only vs. De novo additional lesion set)
Ablation approach:					
• De novo, *n* (%) • Repeated ablation, *n* (%)	• 211 (84.7) • 38 (15.3)	• 0 (0.0) • 38 (100)	• 93 (100) • 0 (0.0)	• 118 (100) • 0 (0.0)	1
Anesthesia protocol:					
• GA • Deep sedation	• 140 (56.2) • 109 (43.8)	• 18 (47.4) • 20 (52.6)	• 43 (46.2) • 50 (53.8)	• 79 (66.9) • 39 (33.1)	0.003
Ablation target:					
• PVI only, *n* (%) • PVI plus additional lesions, *n* (%) • Additional lesions only, *n* (%)	• 106 (42.6) • 142 (57.0) • 1 (0.4)	• 13 (34.2) • 24 (62.2) • 1 (2.6)	• 93 (100) • 0 (0.0) • 0 (0.0)	• 0 (0.0) • 118 (100) • 0 (0.0)	<0.0001
Mapping system used:	82 (32.9)	16 (42.1)	12 (12.9)	54 (45.8)	<0.0001
• Carto™, *n* (%) • Ensite NavX™, *n* (%) • Rhythmia™, *n* (%)	• 20 (24.4) • 23 (28.0) • 39 (47.6)	• 2 (12.5) • 8 (50.0) • 6 (37.5)	• 1 (8.3) • 4 (33.3) • 7 (58.3)	• 17 (31.5) • 11 (20.4) • 26 (48.1)	
Intracardiac echocardiography, *n* (%)	75 (30.1)	14 (36.8)	17 (18.3)	44 (37.3)	0.0031
Sinus rhythm at the procedure, *n* (%)	71 (28.5)	11 (28.9)	43 (46.2)	17 (14.4)	<0.0001
Cardioversion attempt:	127 (51.0)	20 (52.6)	43 (46.2)	64 (54.2)	0.1738
• Successful, *n* (%) • Unsuccessful, *n* (%)	• 113 (89.0) • 14 (11.0)	• 16 (80.0) • 4 (20.0)	• 39 (90.7) • 4 (9.3)	• 58 (90.6) • 6 (9.4)	• 1
Sinus rhythm at the end of the procedure, *n* (%)	230 (92.4)	38 (100)	92 (98.9)	100 (84.7)	0.0002
LA anatomy variants:	13 (5.2)	5 (13.2)	6 (6.5)	2 (1.7)	0.1422
• Left common trunk, *n* (%) • Right middle pulmonary vein, *n* (%)	• 6 (2.4) • 7 (2.8)	• 3 (7.9) • 2 (5.3)	• 2 (2.2) • 4 (4.3)	• 1 (0.8) • 1 (0.8)	
Lab occupancy time, min	110 [80–145]	145 [100–174]	100 [70–133]	110 [80–140]	0.0934
Support time (preparation plus skin-to-skin), min	85 [70–120]	95 [71–150]	78 [65–118]	90 [70–113]	0.0828
Skin-to-skin (primary operator) time, min	70 [60–90]	80 [57–104]	68 [60–90]	70 [59–88]	0.6205
Total fluoroscopy time, min	17 [13–23]	14 [8–24]	17 [13–24]	17 [14-–22]	0.7412
LA dwell time, min	18 [14–25]	20 [16–27]	15 [12–20]	22 [17–28]	<0.0001
Number of PFA deliveries at PVs, *n*	32 [32–38]	32 [32-46]	32 [32-40]	32 [32–34]	<0.0001
Number of PFA deliveries outside of PVs, *n*	16 [14–21]	16 [12-21]	0 [0-0]	16 [14–21]	<0.0001
Number of PFA deliveries, *n*	46 [32–52]	49 [38–60]	32 [32–40]	50 [46–56]	0.0552

fluoroscopic guidance or through a subsequent validation through a high-density mapping system. To the best of our knowledge, this is the largest multicenter study analyzing PeAF patients undergoing LAPWI with PFA. The main findings of our study may be summarized as follows:

1. LAPWI by means of the FARAPULSE™ PFA catheter is feasible, with the electrical isolation endpoint being reached in all cases; 80% of LAPWs were isolated on "first pass" and no further PFA or radiofrequency touch-ups were required after remapping and/or signal assessments+pacing maneuvers.
2. When performed in addition to PVI, LAPWI with this PFA catheter did not significantly prolong overall procedural times in comparison with PVI-only.
3. No major periprocedural complication occurred; only 2.4% minor complications were detected, without differences among groups.

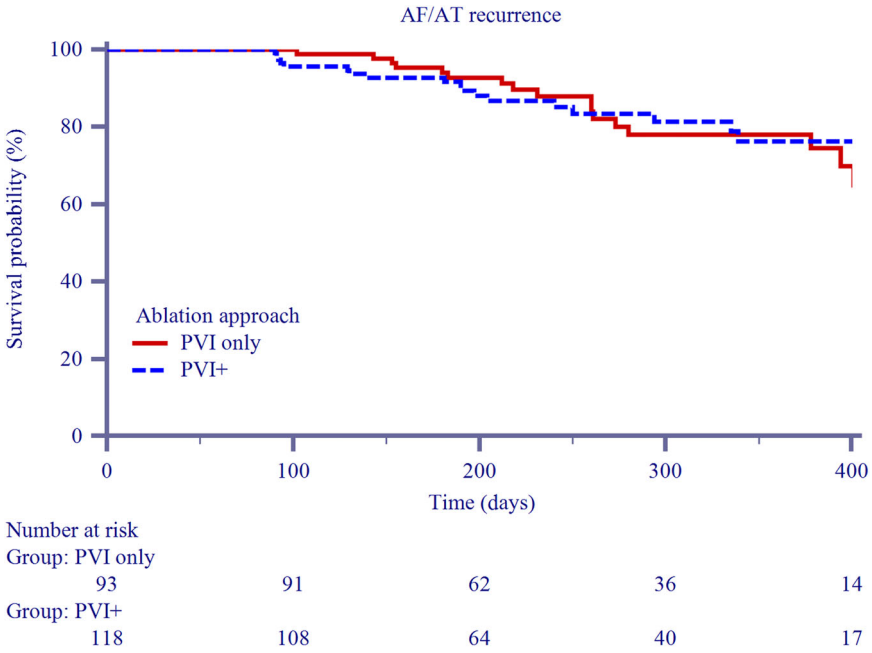

FIGURE 4 Kaplan–Meier curves showing arrhythmic recurrences during follow-up stratified per ablation strategy (red: PVI-only; blue: PVI + LAPWI). LAPWI, left atrial posterior wall isolation; PVI, pulmonary vein isolation.

4. Over a median follow-up up of 273 [191–379] days, 41 patients (16.5%) had an arrhythmic recurrence. No differences were found when stratifying for AF pattern (persistent vs. long-standing persistent) and ablation strategy (PVI-only vs. PVI + LAPWI vs. redo patients).

4.2 | PFA energy for PW isolation

So far, the PFA technology has been used for LAPWI in persistent AF patients only in few cases.[30–33] As demonstrated by Reddy et al.[30] in the first in-human feasibility study, the pentaspline PFA catheter could be maneuvered while flat along the posterior LA in the flower configuration. Its shape and flexibility allow the operator to properly reach the PW and to cover it entirely with few repositioning maneuvers. While Reddy et al. visualized the PFA catheter on electroanatomical mapping in all cases, in addition to fluoroscopic and ICE guidance, we used the mapping system to integrate fluoroscopic navigation in only 32.9% of PVI-only cases and in 45.8% of LAPWI cases ($p < 0.001$).

To the best of our knowledge, this is the first evidence that LAPWI is feasible even with fluoroscopic guidance alone. We observed a reduction in the use of 3D mapping systems over time, with operators increasingly relying on fluoroscopy for LAPWI. A still image of the catheter position before moving it towards another zone allowed operators to achieve adequate LAPWI without the need for 3D mapping. This finding underscores the adequacy of our ablation workflow in obtaining acute LAPWI, leading operators to gain confidence in concluding later phases of our studies without deeming mapping always necessary. Whenever the mapping system was used, electroanatomical imaging of the catheter splines enabled us to monitor the PFA deliveries and guarantee proper coverage of the PW and lesion intersection. Moreover, in the mapping-validated cohort, we were able to properly define the precise extension of the LAPW area when addressing continuous lesions, properly adjacent to each other, connecting the floor, the roof, as well as the inner LAPW. LAPWI gaps were mostly detected at the central LAPW areas (13 out of 23, 56.5%, in the P2-P5-P8 areas, probably being the farther regions from the previous PV energy deliveries; in these areas, additional lesions were provided whenever required. Nevertheless, in all cases the PFA catheter was sufficient to properly address these gaps and no radiofrequency touch-ups were needed. Even in cases of unusual PV ostial anatomy (a left common trunk and with a right accessory PV), the operators were able to achieve LAPWI in conjunction with those structures by using only the PFA system.

4.3 | Clinical implications and safety concerns

Although PVI by means of PFA has proved to be feasible and safe, and a recent randomized trial demonstrated its non-inferiority to thermal ablation,[34] there is evidence that a PVI-only strategy may be suboptimal for arrhythmia control. Indeed, higher recurrence rates have been reported in persistent AF patients when balloon-based technologies are used for PVI.[35,36] The rationale for isolating the LAPW lies on its common embryological origin,[37] which is shared with the arrhythmogenic PV tissue, both being contiguous structures in the LA. However, which additional ablation should be performed, in addition to PVI, in PeAF patients is still controversial; a recent randomized trial[2] suggested that adding radiofrequency LAPWI to PVI during the first ablation procedure was futile, unless rapid LAPW electrical activity was detected during electroanatomical mapping.[38] However, these results need to be confirmed, since several previous attempts to find the "magic bullet" had failed to develop a map-

guided approach to identifying focal AF sources, such as rotors/focal drivers[23] that may sustain persistent AF. On the other hand, previous trials had shown that LAPWI could provide additional benefits[24] over PVI alone in the treatment of PeAF, improving procedural outcome[25] even over long-term follow-up.

One of the critical aspects of the CAPLA trial[2] was that all patients underwent a point-by-point box LAPWI with radiofrequency following PVI. This linear ablation was deemed to be sufficient in most cases, if mapping and pacing maneuvers demonstrated acute LAPWI. However, the "box-only" PW lesion set has often been criticized, since it is prone to the development of electrical gaps, which may lead to entire medium and long-term reconnection of the LAPW if one or more lesions are inconsistent or non-permanent. In addition, box-creating ablation lines might not be sufficient[26] to isolate arrhythmogenic sources that extend to the upper and the lower parts of the floor of the pulmonary wall, and may lead to higher recurrences of postablation AT/AFL/AT.[27] Indeed, in the LIBERATION trial, which showed the superiority of the combined PVI + LAPWI combined approach, complete electrical isolation of the entire LAPW was obtained, with the aim being to reduce the critical LA mass, thereby limiting postablation LAPW reconnections. Nevertheless, this approach may markedly prolong procedural times and expose patients to a theoretical higher risk of periprocedural complications because of the higher number of energy deliveries at the LAPW level.[7] In the CAPLA trial, overall procedural times for reaching PW isolation (with a box lesion setting—the shortest protocol in terms of radiofrequency deliveries) were 142 [SD, 69] mins, while overall procedural times in our LAPWI cohort were 90 [SD 70–113] mins.

Thus, PFA technology may potentially overcome these drawbacks. First, as demonstrated by our ablation workflow and remapping, PFA can achieve entire and homogeneous LAPWI, thus avoiding the potential creation of the box gaps associated with the traditional point-by-point techniques. These gaps have traditionally been claimed to be one the most important determinants of LAPW reconnection in the long-term, leading to suboptimal outcomes.[28] Moreover, the technique adopted in our study frees the operator from concerns regarding the potential esophageal damage that may be caused by prolonged and extensive radiofrequency LAPW ablation. Second, the ability of PFA to overcome layers of adipose tissue could have implications especially along the LA roof, when radiofrequency deliveries is known to be limited. Indeed, in the superior aspect of the LAPW, the subepicardial septo-pulmonary bundle may be separated from the subendocardial septo-atrial bundle by a distinct sheath of adipose tissue of variable thickness.[29] Since adipose tissue has very low electrical conductivity, it may prevent the endocardial radiofrequency delivery from going from the more endocardial septo-atrial bundle to the more epicardial septo-pulmonary bundle. The radiofrequency-induced heating produced at the level of the septo-atrial bundle remains confined to a small issue volume, since the low thermal conductivity of the adipose layer exerts an insulating effect that protects the more epicardial septo-pulmonary bundle from thermal injury, making transmural ablation difficult.[39] However, we were not able to detect differences among groups when comparing PVI-only vs PVI + LAPWI patients, which is consistent with recent findings reported by Turagam et al.[40] It is important to note that the relatively low sample size and the overall short follow-up duration may have limited the statistical power of our study to detect differences regarding the long-term outcomes of these two different ablation strategies. It is worth mentioning that the potential antiarrhythmic effect of LAPWI may manifest more prominently in the long term and after 1 year postablation when compared to PVI-only.[41] Indeed, Aryana et al.[42] enrolling 320 patients treated with cryoballoon (PVI: $n = 160$; PVI + LAPWI: $n = 160$) showed no differences between these two strategies at 12 months, while freedom from all atrial arrhythmias (67.5% vs. 45.0%; $p < 0.001$) and AF (75.6% vs. 55.0%; $p < 0.001$) were significantly greater with PVI + PWI versus PVI alone at 39 ± 9 months of follow-up. Thus, PVI + PWI appears to be associated with greater freedom from recurrent atrial arrhythmias and AF in patients with paroxysmal AF during long-term follow-up > 3 years.

When comparing our results to the PIVOTAL AF trial,[43] we observed a significantly lower number of recurrences in persistent AF patients treated with PVI-only in our cohort (81.7% vs. 55.1% in the PIVOTAL trial). We believe that the differences between these studies may be attributed to the shorter follow-up duration in our study (273 [191–379] days vs. 365 days) and variations in AF recurrence monitoring strategies. The transtelephonic monitoring strategy used in the PIVOTAL trial may indeed be more accurate in detecting AF recurrences compared to our methodology. On the other hand, when comparing the recurrence rate of PVI + LAPW patients in our study (15.3%), our findings are comparable to those reported by Badertscher et al.[44] who showed a 15% recurrent AF/AT rate during a median follow-up of 144 (94–279) days. This suggests that adding LAPWI may optimize the ablation effect of PVI-only. However, it is worth noting that in the study by Badertscher et al. first-pass isolation was controlled using a multipolar mapping catheter, which may not guarantee better outcomes than our approach using a fluoroscopy-only approach in 54.2% of cases, confirming the effectiveness of our workflow. Third, preclinical data gathered from vegetable models and histopathology have shown that PFA lesions are composed of organized, homogeneous fibrosis replacing the myocardium with well-demarcated border zones, while radiofrequency lesions appears to be disorganized and heterogeneous with a greater inflammatory response.[29,45] This homogeneous appearance, which was revealed by our 3D-mapping, is in line with a report by Gunawardene et al.[31] who found that high-density-mapped PFA lesions were highly homogenous with only minor and small fractionated areas of along the border of ablation sites. The lack of these fractionated and fragmentated potentials at the border or within the PFA acute lesions might hamper the often-advocated proarrhythmic effects generated by incomplete or suboptimal LAPW radiofrequency energy deliveries and leading to postablation atypical AFL/AT.

5 | LIMITATIONS

Most limitations of this study are related to its intrinsic non-randomized nature. However, this was a prospective study, in which AF ablation and patient management were performed according to the standard-of-care of each center. ATHENA was indeed designed to evaluate the real-world use and adoption of a different ablation technology for an all-comer AF patient population. We acknowledge that relying solely on clinical history in deciding to perform PVI-only versus PVI-LAPW isolation may introduce potential biases, particularly in comparison to a randomized study directly comparing these two methodologies. However, it is important to note that the evidence surrounding LAPWI is currently unclear. Therefore, our registry serves as a reflection of real-world data, analyzing the actual multicenter scenario and providing insight into current clinical practices in several high-volume centers utilizing PFA. Second, the nonhomogeneous use of 3D-mapping systems and ICE use might have affected the LAPWI assessment, that in some cases was validated with the voltage mapping and in some other cases with pacing maneuvers. Finally, the medium and long-term assessment of the clinical outcomes of LAPWI is beyond the scope of our study and the short-term follow-up represents a significant limit of our analysis. Future studies with longer follow-up are surely needed to describe if LAPWI with PFA may improve arrhythmic freedom from recurrences compared to a traditional PVI-only strategy.

6 | CONCLUSIONS

Complete LAPWI with PFA demonstrates feasibility, rapidity, and safety in real-world practice, offering a viable alternative for PeAF patients. LAPWI is achievable even with a fluoroscopy-only method and does not significantly extend overall procedural times. Further studies with longer follow-up are needed to assess the benefits of LAPWI in PeAF patients regarding freedom from arrhythmic recurrences.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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