

Brazilian Registry of Pulsed Field Catheter Ablation for the Treatment of Patients with Atrial Fibrillation

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Abstract

Background: Pulsed field ablation (PFA), a new catheter-based, non-thermal ablation technique, enhances the safety and efficacy of catheter ablation of atrial fibrillation (AF) compared to conventional thermal methods. While widely adopted in Europe and the United States, its application in Brazil is recent and remains undocumented.

Objective: This study reports the initial multicenter Brazilian experience with the pulse field ablation to treat patients with AF, emphasizing its rapid adoption and short learning curve.

Methods: A retrospective analysis of 394 consecutive procedures, performed by 60 operators across multiple Brazilian centers, was conducted. Data encompassed patient demographics, procedural metrics, imaging modalities, and ablation outcomes. A sub-analysis compared high-volume operators (n=139 procedures) with others (n=255). All statistical tests were two-tailed, with a p-value threshold of <0.05 for statistical significance.

Results: Paroxysmal AF was predominant (62%), with pulmonary vein isolation (PVI) only as the primary lesion set in 54%. General anesthesia was near-universal (98%), and no major complications occurred. High-volume centers had significantly shorter procedure and ablation times (82 ± 27 vs. 131 ± 76 minutes; $p < 0.001$ and 33 ± 14 vs. 50 ± 33 minutes; $p < 0.001$, respectively), alongside fewer additional lesions after remapping (7% vs. 30%; $p < 0.001$), suggesting a rapid learning curve.

Conclusion: Pulsed field ablation demonstrates high acute efficacy, safety, and ease of adoption in Brazil, with a notably short learning curve, as evidenced by the efficiency of high-volume operators. Long-term outcome studies are warranted.

Keywords: Atrial Fibrillation; Catheter Ablation; Brazil.

Introduction

Pulsed field ablation (PFA) represents a transformative advance in the management of atrial fibrillation (AF). This new, catheter-based, non-thermal technique uses ultrafast electrical

pulses to cause irreversible electroporation in cardiac myocytes, selectively targeting heart tissue. By avoiding thermal energy, PFA eliminates rare but serious complications of traditional AF ablation, such as left-atrial esophageal fistula, permanent phrenic nerve paralysis, and pulmonary vein stenosis, while improving procedural efficacy and efficiency.¹ The MANIFEST-PF registry, the largest European multicenter study, reported a survival free of AF curve of 78% after a single procedure, with higher efficacy in paroxysmal AF (82%) than persistent AF (71%) and a median procedure time of 61 minutes.² Other early trials further validated PFA's efficacy and safety.^{3,4}

In Brazil, AF is estimated to impact approximately 5 million individuals, with an increasing prevalence due to an aging

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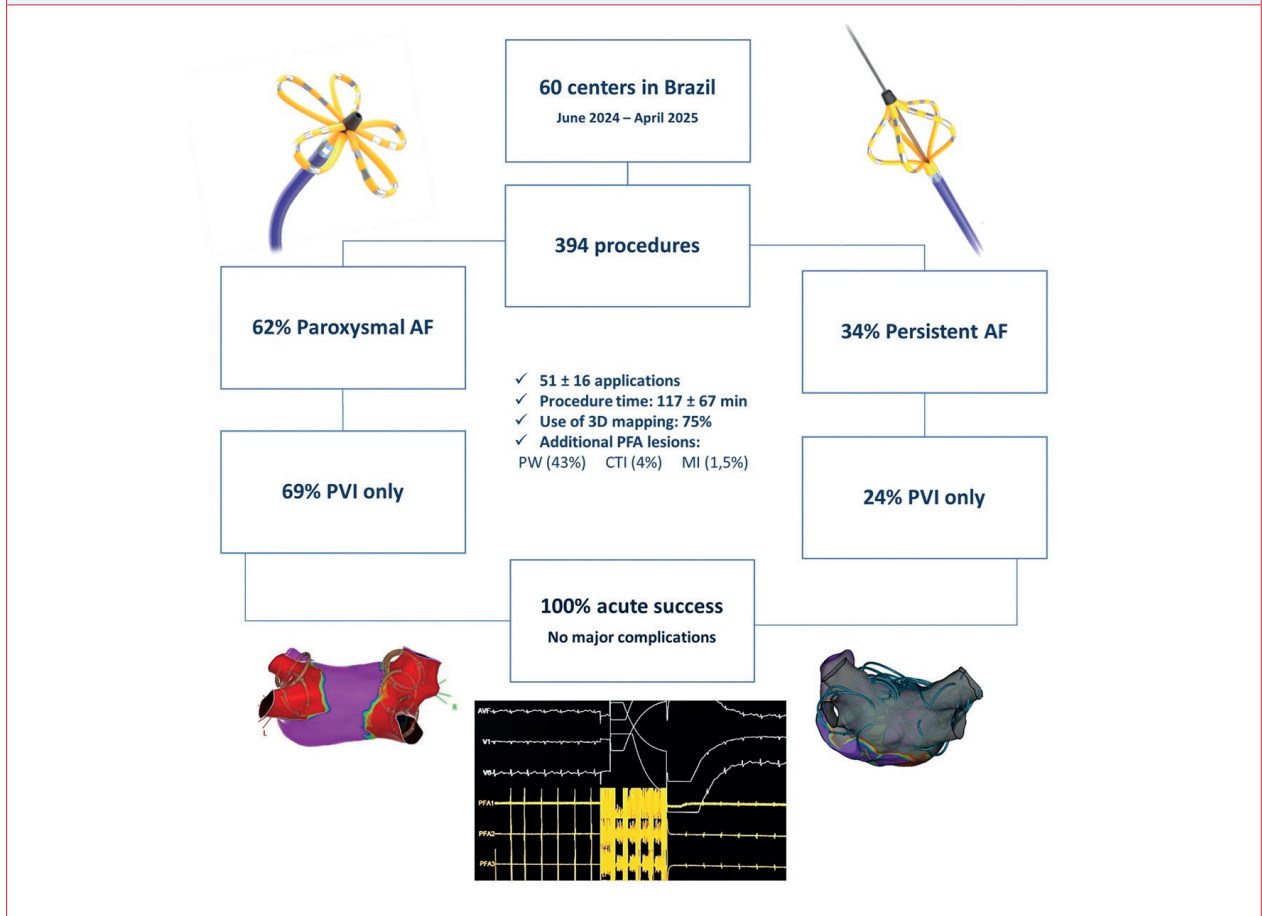
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Central Illustration: Brazilian Registry of Pulsed Field Catheter Ablation for the Treatment of Patients with Atrial Fibrillation



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The Brazilian PFA Registry summarizes 394 pulsed field ablation (PFA) procedures performed across 60 centers in Brazil from June 2024 to April 2025. Three-dimensional maps depict pulmonary vein isolation (left side - Carto) and additional posterior wall isolation (right side - Navx) achieved with PFA. Intracardiac tracings (bottom) show PFA delivery, with real-time electrical activity recorded from within a pulmonary vein (orange signals) vanishing after ablation, leaving only far-field signals. PVI: pulmonary vein isolation; AF: atrial fibrillation; CTI: cavotricuspid isthmus; MI: mitral isthmus; PW: posterior wall.

population and the rising incidence of associated risk factors, such as hypertension and diabetes.⁵ However, access to catheter ablation remains constrained, particularly in regions beyond major urban centers, owing to elevated costs, a scarcity of specialized electrophysiology facilities, and inadequate training of operators in advanced ablation techniques. The approval of the first PFA system by the Brazilian Health Regulatory Agency (ANVISA) in April 2024 may represent a potential change in addressing these challenges.

While widely adopted worldwide, PFA use in Brazil is recent and remains undocumented. Due to variations in healthcare infrastructure, disparities in operator experience, and a patient population with potentially higher comorbidities driven by socioeconomic factors,⁶ PFA utilization in Brazil may diverge from that of the United States, Asia, and Europe

regarding its workflow and long-term results. This study describes the first 394 PFA procedures performed in Brazil across multiple centers.

Methods

This voluntary, prospective registry was derived from 394 consecutive procedures conducted between June 18, 2024, and April 29, 2025, by 60 participating operators. Patient demographics, AF type, procedural metrics, imaging modalities, number of PFA applications, type of lesion sets, and whether additional lesions were needed upon remap were analyzed. All data were stored anonymously, including patient and operator identification. Total procedure time was defined as the duration from vascular access to catheter removal and ablation time from the first to the last PFA

application. Additionally, the use of electroanatomic mapping systems (EAM) and intracardiac echocardiography (ICE), along with fluoroscopy, was also analyzed. A secondary analysis comparing the 3 highest volume operators (Group I = 139 patients – 35%) with the remaining Group II (255 patients – 65%) was performed to assess the impact of a learning curve with this new approach.

Catheter, transeptal sheath, and ablation generator for pulsed field ablation

The Ablation Catheter is an over-the-wire, pentaspline catheter (12F) with a versatile distal end capable of adopting 3 configurations: a “basket”, a “flower”, and an “olive” shape. These configurations facilitate adaptation to a wide range of pulmonary vein anatomies, ensuring optimal tissue contact and procedural reproducibility across diverse patient populations. The catheter’s design supports the assessment of intra-spline bipolar electrograms, allowing integration with several cardiac mapping systems to provide real-time visualization of catheter placement, shape, and rotation.

Via a transeptal approach, a bidirectional steerable sheath with 180 degrees of articulation is utilized to navigate the ablation catheter to targeted cardiac anatomy (OD = 16.8F and ID = 13F). The sheath requires a constant heparinized saline infusion to prevent thrombus formation and air embolism. The catheter is compatible with an ablation generator, which delivers proprietary bipolar and biphasic waveforms (Figure 1).

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Statistical analysis

The statistical analysis employed a primarily descriptive approach. Continuous variables were reported as means $\pm$ standard deviations (SD), as all variables exhibited normal distribution, confirmed by the Shapiro-Wilk test. Categorical variables were presented as frequencies and percentages. Comparative analyses were conducted using the unpaired Student’s t-test for continuous variables and the Chi-squared test for categorical variables. All statistical tests were two-tailed, with a p-value threshold of <0.05 for statistical significance. Data analyses were performed using SPSS software (version 29.0).

The statistical methodology for analyzing the learning curve of PFA procedures excluded entries with missing dates, total procedure and ablation times, and approximated operator experience with procedure numbers while categorizing case complexity as “Low” (paroxysmal AF) or “High” (persistent/re-do AF). A logarithmic regression model was fitted to total procedure time against procedure number for each operator, capturing rapid initial improvements and slower gains as experience increased, with parameters estimated via least squares. Average time reductions and plateau points were calculated. Variability was assessed through standard deviations, case complexity comparisons, and correlation. The methodology assumes a power-law learning pattern and independent procedures, with limitations including data gaps for low-volume operators and simplified complexity categorization.

Results

All the results are detailed in Table 1. The mean age was 65 ± 12 years, and 64% of the cohort were male. Paroxysmal AF was the primary indication in 62%, followed by persistent AF in 34% of the patients.

Pulmonary vein isolation-only (PVI) was the dominant lesion set requiring 44 ± 10 PFA applications and an ablation time of 37 ± 16 minutes. Posterior wall isolation was performed in 168 patients (43%) either during the index or a redo procedure, requiring 58 ± 15 applications and 45 ± 28 minutes of PFA.

General anesthesia was used in all but 8 cases (deep sedation). Median total procedure time was 113 ± 67 , and ablation time was 44 ± 29 minutes. Fluoroscopy-guided ablation was used in most procedures, and 47 procedures (22%) were exclusively guided by fluoroscopy (mean time: 25 ± 10 minutes). A combination of EAM and ICE was utilized in 92 procedures (25%), while EAM without ICE was used in 184 cases (50%). Transesophageal echocardiography (TEE) was used in about 30% of procedures to guide transeptal puncture or assist with catheter positioning around the pulmonary veins, as reported by the operator, though its use was not consistently documented.

Fluorless procedures were conducted in 47 (12%) patients. Fluorless procedures had a significantly higher number of applications (74 ± 22 vs. 48 ± 12 , $p < 0.001$), longer ablation and total procedure times (53 ± 14 vs. 40 ± 25 minutes, $p = 0.002$ and 145 ± 37 vs. 106 ± 67 minutes, $p < 0.001$, respectively) as compared to procedures using fluoroscopy.

Remap was performed in all patients in whom EAM was utilized to guide the procedure, and additional PFA applications were deemed necessary in 26% of them as per the operator’s discretion. PFA applications were also utilized to ablate the cavotricuspid isthmus (CTI) in 16 patients (4%) and the mitral isthmus (MI) in 6 patients (1.5%). PFA ablation was performed in 14 patients who had previous RF ablation (4%). No major complications were reported during this initial series.

A summary of the main findings of the study is presented in the central illustration.

Secondary analysis

A secondary analysis comparing the 3 highest volume operators (Group I = 139 patients – 35%) with the remaining

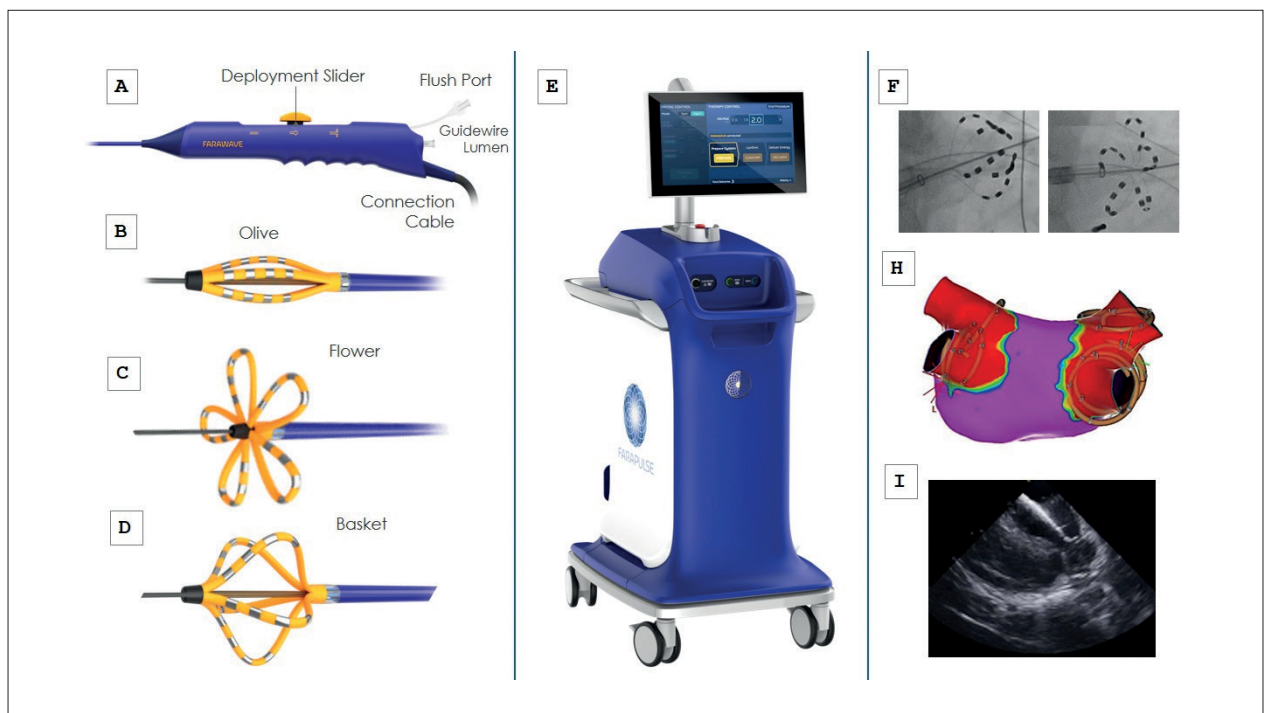


Figure 1 – The Pulsed Field Ablation System (FARAPULSE™ - Boston Scientific, Natick, USA) features a 12F, over-the-wire, irrigated catheter (FARAWAVE™ - Panel A) with a versatile electrode array that can form an olive (panel B), flower (panel C), or basket (panel D) shape to conform to the pulmonary vein ostia. The catheter is guided into the left atrium through a transseptal puncture using a 16.8F steerable sheath (FARADRIVE™). The system delivers microsecond-scale electrical pulses (1.5–2 kV) in a controlled, biphasic waveform, generated by the FARASTAR™ Ablation Generator (panel E). Each application consists of a pulse train with 5 individual pulses, each lasting 50–100 microseconds, delivered within a 100–200 millisecond window. Typically, 4–8 applications per pulmonary vein ensure complete isolation. This process induces electroporation, selectively forming permanent pores in cardiomyocyte membranes, which will eventually result in cell death by apoptosis (panel G). The ablation catheter can be visualized by fluoroscopy (panel F – frames provided by A dal Forno), at the EAM (panel G – provided by BM May), and by ICE (panel H – frame provided by EB Saad). PA: Postero-anterior; PV: pulmonary veins; L: left; R: right.

Group II (255 patients – 65%) was performed to assess the impact of a learning curve with this new approach (Figure 2).

There was a higher prevalence of male sex in Group I (High-volume operators), but no differences in age. Total procedure time, ablation time, and the number of PFA applications were significantly lower in Group I as compared to Group II (Table 2). Moreover, Group I had reduced fluoroscopy time and required a lower number of additional post-remapping PFA applications.

Learning curve

The learning curve analysis for PFA procedures, based on a dataset of 125 procedures, evaluated total procedure time and ablation time, considering operator experience, case complexity, and procedure volume. A logistic regression model quantified the learning curve, showing a steep initial decline in procedure time over the first 5–10 procedures, with most operators achieving a plateau after 10–15 procedures, where time reductions fell below 5%. Average time reductions ranged from 5 to 10 minutes per case for high-volume operators. Total procedure time ranged from 42 to 240 minutes (median 90 minutes), and ablation time from 11 to 180 minutes (median

34 minutes), with persistent AF cases requiring longer times (mean 105 minutes vs. 80 minutes for paroxysmal AF).

Discussion

The first Brazilian multicenter, prospective, voluntary registry of 394 PFA consecutive procedures for AF shows high acute efficacy in line with several international studies. No major complications were reported in our series, potentially related to our small sample size and reporting bias due to the voluntary nature of the registry. However, these results are similar to PULSED AF (0.7%) and surpass MANIFEST-PF/ADVENT trials (2.1%).^{2,3,7} Total procedural and ablation times were longer than in MANIFEST-PF but comparable to ADVENT (106 minutes total, 29 minutes ablation) and SPHERE AF (101 minutes total, 46 minutes ablation).^{2,3,8}

High-volume operators demonstrated significantly shorter procedure and ablation times, with fewer additional lesions, consistent with EU-PORIA and U.S. findings.⁹ A steep learning curve suggests a seamless integration of this novel technology into clinical practice in Brazil.

Original Article

Table 1 – Clinical and Procedural Characteristics of Pulsed Field Ablation Procedures

Characteristic	Value
Number of Procedures / Operators	394 / 60
Age (years, mean $\pm$ SD)	65 $\pm$ 12
Male, n (%)	252 (64)
General Anesthesia, n (%)	386 (98)
Type of atrial fibrillation, n (%)	
Paroxysmal	244 (62)
Persistent	136 (34)
Redo	14 (4)
Total Procedure Time (min $\pm$ SD)	113 $\pm$ 67
PVI only	100 $\pm$ 41
PVI + PWI	117 $\pm$ 87
Ablation Time (min $\pm$ SD)	44 $\pm$ 29
PVI only	37 $\pm$ 16
PVI + PWI	45 $\pm$ 28
Number of Applications (n $\pm$ SD)	51 $\pm$ 16
Imaging Techniques, n (%) ¹	
Fluoroscopy Only	84 (22)
Fluoroscopy + Mapping	184 (50)
Fluoroscopy + Mapping/ICE	92 (25)
Fluoroscopy + ICE	8 (3)
Lesion Sets, n (%)	
Pulmonary Vein Isolation	212 (54)
Posterior Wall Isolation	168 (43)
Additional Lesions Post-Remapping ²	72 (26)
Complications	Not reported

¹ Among patients with valid data (n = 372). ² Among patients who utilized mapping (n = 276). Values are n (%) or mean $\pm$ SD. PVI: pulmonary vein isolation; PWI: posterior wall isolation; ICE: intracardiac echocardiography.

General anesthesia

Despite the feasibility of performing the procedure under deep sedation, the near-universal use of general anesthesia in this registry also warrants consideration. GA ensures patient immobility, which is critical for accurate catheter positioning, stability, and lesion delivery.¹⁰ It facilitates the use of ICE and mapping systems by minimizing patient movement artifacts

and enhancing operator comfort during complex or prolonged procedures. Furthermore, general anesthesia ensures patient comfort, eliminating the risk of pain or awareness during ablation, which can occur with inadequate sedation. GA has also been associated with better long-term outcomes of radiofrequency catheter ablation of AF.¹¹ However, GA has notable drawbacks, including higher costs due to the need for an anesthesiologist and specialized equipment, increased procedural time for induction and recovery, and potential risks such as airway complications and prolonged recovery time in patients with comorbidities. In contrast, deep sedation may reduce costs and procedural time while avoiding anesthesia-related risks, but it carries the challenge of maintaining consistent sedation depth, which could lead to patient movement or discomfort, potentially compromising procedural accuracy. The preference for general anesthesia in Brazil may reflect the availability of anesthesiology expertise in urban centers and a cautious approach to adopting a novel technology like PFA, where precision is paramount. This practice differs from some international settings,² especially in Europe, where deep sedation is more common (82%).

Fluoro-less PFA

Only 47 (12%) procedures were performed without fluoroscopy guidance in our cohort. A typical AF ablation using fluoroscopy delivers approximately 15 mSv of radiation, comparable to 5–7 years of natural background radiation of about 2–3 mSv annually. Fluoro-free AF ablation eliminates radiation exposure while achieving similar durable PVI and complication rates as fluoroscopy-guided methods.¹² EAM and ICE's precision enhances catheter navigation and lesion accuracy, outweighing fluoroscopy's speed and familiarity but requires specific operator expertise. While fluoroscopy seems to enable faster procedures and fewer energy deliveries, its radiation risks make fluoro-less procedures a safer and more advanced choice, prioritizing long-term health over procedural brevity. Nevertheless, no randomized clinical trials

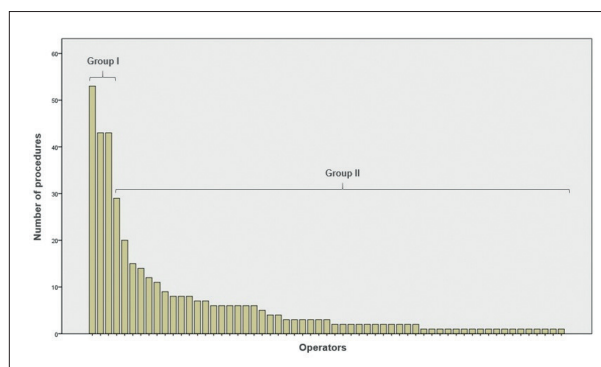


Figure 2 – Distribution of procedures by operator. The x-axis represents the operators, while the y-axis indicates the total number of procedures performed. Group I (left) includes operators with higher procedure counts, peaking above 40 procedures, indicating high-volume operators. Group II (right) includes operators with fewer procedures, mostly below 10, reflecting lower-volume centers.

have yet directly compared fluoro-less to fluoroscopy-guided PFA ablation.

ICE during PFA

The use of ICE introduces significant cost considerations, with single-use ICE catheters costing approximately \$1,500–\$3,000 per procedure, in addition to the capital expense of ultrasound equipment. In Brazil, where healthcare resources are often constrained, particularly in non-urban centers, these costs may limit ICE adoption, potentially explaining why only 25% of procedures relied on this technology. Notably, ICE is also not routinely used in many European countries, where fluoroscopy and electroanatomic mapping systems dominate due to cost constraints and established workflows.^{9,13} However, the use of ICE during an AF ablation procedure was significantly associated with a lower incidence of complications and repeat ablation,¹⁴ highlighting the need for cost-effectiveness analyses to justify its use in PFA cases. The reuse of the ICE catheter, as currently done worldwide, would significantly reduce the costs in Brazil.

High-volume operators

A key highlight in our registry is the steep learning curve associated with PFA adoption, particularly evident in the performance of high-volume operators who achieved significantly shorter procedure and ablation times and a lower rate of additional lesions post-remapping. These metrics suggest enhanced procedural efficiency and precision with increased experience, corroborated by external studies reporting reduced procedure times in high-volume centers and a short learning curve after 10 procedures.¹⁵

Comparative analysis of pulsed field ablation for atrial fibrillation across regions

PFA for AF ablation shows consistent efficacy across Europe, the United States, Brazil, and Asia, despite differences in procedural approaches. The MANIFEST-PF registry reported a 78% one-year freedom from atrial arrhythmia recurrence in diverse AF patients, with limited use of ICE, EAM, or general anesthesia, indicating PFA's effectiveness is not heavily reliant on these tools. In contrast, U.S. centers frequently employ ICE and EAM for detailed imaging, as seen in the ADVENT trial, which reported a 73.3% one-year freedom from a composite endpoint (recurrent arrhythmias, antiarrhythmic drug use, cardioversion, or repeat ablation).

Safety profiles are equally robust across regions. The EU-PORIA registry noted a 3.6% complication rate, with no esophageal issues, pulmonary vein stenosis, or persistent phrenic nerve palsy. The MANIFEST-17K study in Europe reported major complications in 1% of 17,642 patients, mainly pericardial tamponade (0.36%) and vascular events (0.30%). The U.S. ADVENT trial met its safety endpoint but reported one death due to cardiac perforation, emphasizing the need for skilled operators.

In Brazil, 75% of PFA procedures used EAM, compared to 33% in Europe's EU-PORIA registry. EAM supported posterior wall ablation in 43% of Brazilian cases, leading to longer procedure and ablation times, similar to an Asian registry

Table 2 – Comparison between High and Low Volume Operators

Variables	Group I (n=139)	Group II (n=255)	p-value
Age (n ± SD)	66 ± 11	64 ± 14	0.29
Male (%)	64	50	<0.001
Paroxysmal AF (%)	62	61	0.24
Total Procedure Time (min ± SD)	82 ± 27	131 ± 76	<0.001
Ablation Time (min ± SD)	33 ± 14	50 ± 33	<0.001
Fluoroscopy Time (min ± SD)	23 ± 9	31 ± 18	<0.001
Additional Lesions After Remapping (%)	7	30	<0.001
Número de aplicações (n ± DP)	48 ± 10	53 ± 19	0.005

Group I: The three highest volume operators according to Figure 2. Values are % or mean ± SD. AF: atrial fibrillation; Min: minutes.

where EAM (82%) and ICE (90%) use resulted in an 88% one-year success rate.¹⁶ Brazilian data revealed a 26% rate of additional lesions during remapping post-ablation, suggesting incomplete pulmonary vein or posterior wall isolation. This highlights potential risks of relying solely on fluoroscopy, especially in low-volume centers, which may increase AF recurrence due to suboptimal lesion sets.

Limitations

This first Brazilian PFA registry has several limitations, including the absence of long-term follow-up data on AF recurrence and variability in operator experience and center protocols. The voluntary submission of data introduces potential selection bias, as operators may have reported only successful cases. Future research should prioritize longitudinal outcomes, cost-effectiveness of imaging and anesthesia strategies, and the optimization of training to reduce variability among operators.

Conclusion

The pulse field ablation demonstrates high acute efficacy, safety, and ease of adoption in Brazil, with a remarkably short learning curve, as evidenced by the superior efficiency of high-volume operators. These findings position PFA as a new tool in AF ablation, with the potential to enhance patient outcomes and procedural scalability. Long-term studies are essential to confirm its long-term results and optimize clinical protocols.

Author Contributions

Conception and design of the research: May BM, Araujo Junior N, Boghossian SHC, Atie J, Maciel WA, Hardy

CA, Dal Forno ARJ, Saad EB, Munhoz C, de Paola AAV, Zimerman A, d'Avila A; Acquisition of data and Critical revision of the manuscript for content: May BM, Araujo Junior N, Boghossian SHC, Atie J, Maciel WA, Hardy CA, Dal Forno ARJ, Saad EB, Munhoz C, de Paola AAV, Scanavacca M, Zimerman A, Vasconcelos JTM, d'Avila A; Analysis and interpretation of the data: May BM, Araujo Junior N, Dal Forno ARJ, Zimerman A, d'Avila A; Statistical analysis: May BM, Araujo Junior N, Zimerman A, d'Avila A; Obtaining financing: Araujo Junior N; Writing of the manuscript: May BM, Araujo Junior N, Dal Forno ARJ, d'Avila A.

Potential conflict of interest

No potential conflict of interest relevant to this article was reported.

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Study association

This study is not associated with any thesis or dissertation work.

Ethics approval and consent to participate

This study was approved by the Centro de Ensino e Pesquisa do Instituto de Cardiologia de Santa Catarina (CEP # 113) under the protocol number CAAE: 89229325.1.0000.0113. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013.

Use of Artificial Intelligence

The authors did not use any artificial intelligence tools in the development of this work.

Data Availability Statement

The underlying content of the research text is contained within the manuscript.

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