# Atrial fibrillation laser balloon ablation: Multicenter international study

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**BACKGROUND** Durable pulmonary vein isolation (PVI) for atrial fibrillation (AF) remains challenging. The visually guided laser balloon (VGLB) is a unique single-shot technology designed to simplify PVI.

**OBJECTIVE** This study aimed to assess the real-world safety and long-term effectiveness of the third-generation VGLB system for treating paroxysmal and persistent AF.

**METHODS** This prospective, multicenter registry enrolled 427 patients undergoing VGLB-PVI. Safety was assessed in all patients, whereas the primary effectiveness endpoint (12-month freedom from AF) was analyzed in 392 patients who completed follow-up. Cox regression models were used to identify predictors of recurrence.

**RESULTS** Acute PVI was achieved in all targeted veins. The system demonstrated a favorable safety profile; permanent phrenic nerve palsy occurred in 1 patient (0.2%). After a 3-month blanking period, the 12-month freedom from AF recurrence off antiarrhythmic drugs was 73.8%. This rate increased to 77.7% for procedures performed after the initial 15-case operator learning curve. Multivariate analysis identified procedures within the learning curve (hazard ratio [HR] 1.68), congestive heart failure (HR 2.04), and anatomic variants (HR 1.79) as independent predictors of recurrence.

**CONCLUSION** In this large, real-world registry, third-generation VGLB ablation is a safe and effective strategy for achieving long-term freedom from AF. Operator experience beyond the initial learning curve is a key determinant of success, confirming VGLB as a viable and effective PVI option.

**KEYWORDS** Atrial fibrillation; Catheter ablation; Laser balloon; Pulmonary vein isolation; Effectiveness; Safety; Learning curve; Single-shot ablation

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## Introduction

Atrial fibrillation (AF) is the most prevalent sustained cardiac arrhythmia worldwide, imposing a substantial burden on patients and health care systems through an increased risk of stroke, heart failure (HF), and mortality.[1] Catheter ablation aimed at achieving durable pulmonary vein

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## KEY FINDINGS

- In a large, real-world registry of 427 patients, laser balloon ablation demonstrated a favorable safety profile, including a 0.2% rate of permanent phrenic nerve palsy. It also achieved a 12-month arrhythmia-free survival of 73.8% off antiarrhythmic drugs.
- Success at 12 months is independently predicted by 3 key factors: the patient's clinical status (presence of congestive heart failure), the patient's unique anatomy (presence of pulmonary vein variants), and the operator's procedural experience (being within the learning curve).
- Congestive heart failure is an independent predictor of recurrence (hazard ratio [HR] 2.04). It signifies a more advanced atrial cardiomyopathy, where pulmonary vein isolation alone may be insufficient for long-term rhythm control. This highlights the importance of managing comorbidities and selecting the ablation technology in relation to the patient's clinical profile.
- Complex pulmonary vein anatomy is not only a technical challenge but also an independent predictor of long-term arrhythmia recurrence (HR 1.79), highlighting the importance of anatomic assessment in risk stratification.
- Operator experience has a critical and quantifiable impact on outcomes; procedures performed beyond the first 15 institutional cases were independently associated with a significantly higher rate of 12-month success.

isolation (PVI) has become a cornerstone of rhythm control therapy, demonstrating superiority over antiarrhythmic drugs (AADs) for improving quality of life and reducing arrhythmia burden.[2–6]

Over the past decade, the landscape of AF ablation has been revolutionized by single-shot technologies designed to improve procedural efficiency and safety compared with traditional point-by-point radiofrequency ablation. The cryoballoon was the first such technology to gain widespread adoption,[7] and more recently, pulsed-field ablation (PFA) has emerged as another alternative.[8] Concurrently, the visually guided laser balloon (VGLB) system was developed, offering a unique paradigm. The third-generation HeartLight X3 system integrates several key features: a compliant, variable-diameter balloon for optimal adaptation to diverse pulmonary vein (PV) anatomies, a 980 nm laser for energy delivery, and, crucially, a direct endoscopic view. This allows operators to visually assess tissue contact and lesion formation in real time, a feature intended to optimize PVI durability (Figure 1).[9,10] Furthermore, a motorized function (RAPID mode) facilitates the creation of continuous circumferential lesions.

Although the effectiveness and safety of VGLB have been validated in previous studies, including randomized trials,[11] a deeper understanding of the factors that predict long-term success in a large, contemporary, real-world setting is essential. The outcome of any ablation procedure is not determined by the technology alone but by a complex interplay of 3 critical domains: the patient's clinical substrate (eg, HF, AF type), the specifics of procedural execution (eg, operator experience), and the patient's unique anatomy (eg, venous variants). Identifying which of these factors truly drive long-term success is fundamental for refining patient selection and procedural strategies.

The Atrial Fibrillation Laser Balloon Ablation: Multicenter International Study was designed to address this need by leveraging a large, prospective, multicenter international registry. The primary objective of this analysis is to identify the key clinical, procedural, and anatomic predictors of 12-month arrhythmia-free survival in patients treated with the third-generation VGLB system, to provide clinicians with data for risk stratification and the management of expectations of this technology in the modern era of AF ablation.

## Methods

### Study design and population

This prospective, nonrandomized, multicenter study enrolled 427 consecutive patients undergoing a first-time AF ablation with the third-generation VGLB system at 9 experienced European centers (8 in Italy and 1 in Germany) between September 2020 and December 2022. The study was conducted in accordance with the Declaration of Helsinki and received approval from the local ethics committees at all participating sites. All patients provided a written informed consent.

The safety analysis was performed on the full cohort (n = 427). The primary effectiveness analysis was restricted to the 392 patients with available follow-up data.

Inclusion criteria were aligned with contemporary European Society of Cardiology guidelines for AF ablation.[12] Key exclusion criteria were the presence of a left atrial thrombus, recent cardiac surgery (<3 months), or severe comorbidities compromising prognosis.

Baseline patient characteristics were defined as follows: HF as a previous clinical diagnosis according to the universal definition and classification of HF[13] and obesity as a body mass index of $\geq$30 kg/m$^2$. We performed cardiac chamber quantification, including measurement of left atrial enlargement, according to European Association of Cardiovascular Imaging recommendations.[14]

### The ablation procedure

All procedures were performed using the third-generation HeartLight X3 VGLB system (CardioFocus, Inc). The VGLB catheter (12F) was introduced via a 16F steerable sheath. The system features a compliant balloon with an integrated endoscope providing direct visualization of the PV

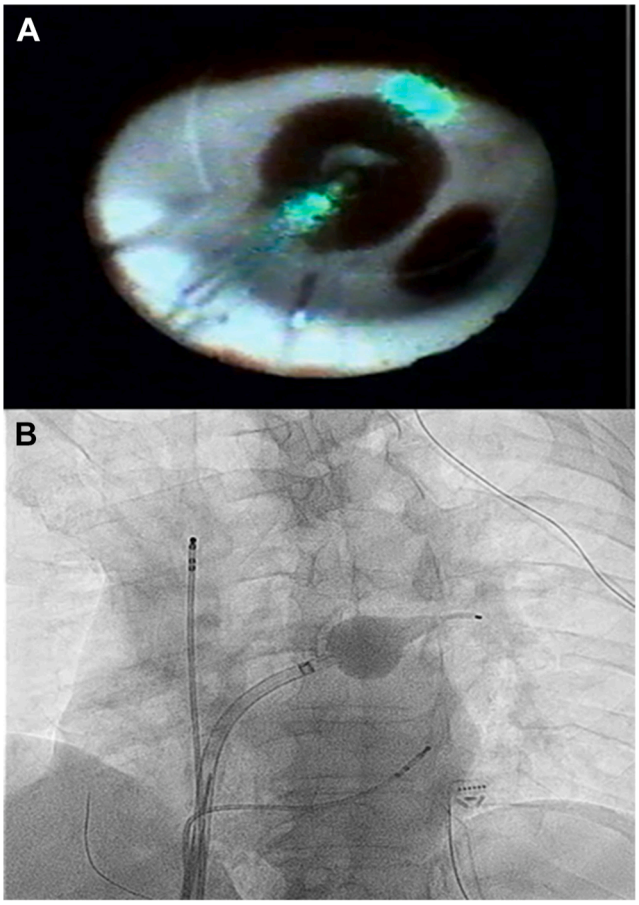


**Figure 1** **A:** Direct visualization of the left inferior pulmonary vein by means of the endoscope embedded in the third-generation VGLB. **B:** Fluoroscopy of the laser balloon engaging the left superior pulmonary vein. VGLB = visually guided laser balloon.

antrum. Laser energy (980 nm diode) is delivered to create circumferential lesions.

An automated RAPID mode, which motorizes the laser beam rotation, was used at the operator's discretion to facilitate continuous lesions. The decision not to use RAPID mode for 100% of lesions in all cases was multifactorial, stemming from operator preference for precise manual energy titration in specific regions (eg, near the phrenic nerve) or in veins with challenging anatomies where manual guidance was perceived to ensure better tissue lesions. To minimize phrenic nerve injury risk during right-sided PV ablation, continuous high-output pacing was performed from the superior vena cava, with immediate cessation of energy delivery upon any reduction in diaphragmatic contraction. All procedures were conducted under deep sedation or general anesthesia.

The institutional learning curve was defined a priori as the first 15 procedures at each center.

### Follow-up and end points

After the procedure, patients entered a 3-month blanking period. Scheduled follow-up included clinical evaluation and 24-hour Holter monitoring at 3, 6, and 12 months.

The primary safety endpoint was the incidence of major procedure- or device-related adverse events. The primary effectiveness end point was freedom from arrhythmia recurrence at 12 months. Recurrence was defined as any documented episode of AF, atrial flutter, or atrial tachycardia lasting >30 seconds on a 12-lead electrocardiogram, Holter monitoring, or cardiac implantable electronic device interrogation, occurring after the blanking period and in the absence of AAD therapy.

### Statistical analysis

Continuous variables are presented as median and interquartile range (IQR), and categorical variables as counts and percentages. The Kaplan-Meier method was used to estimate freedom from arrhythmia recurrence. To identify predictors of recurrence, a Cox proportional hazards regression model was used. First, univariate analysis was performed for each potential clinical, procedural, and anatomic predictor. Variables with $P < .05$ in the univariate analysis or with clinical relevance were then entered into a multivariate model, stratified by center, to identify independent predictors. A 2-sided $P < .05$ was considered statistically significant. All analyses were performed using Stata software version 17.0 (StataCorp, TX).

## Results

### Baseline characteristics and procedural data

The final safety cohort consisted of 427 patients. The median age was 62 years (IQR 55–69), and 309 (72.4%) were male. Persistent AF was present in 119 patients (27.9%), a history of HF was documented in 48 (11.2%), and moderate to severe left atrial enlargement was found in 116 (27.1%). Anatomic variants of the PVs were identified in 93 patients (21.8%). A total of 135 procedures (31.6%) were performed within the predefined institutional learning curve of the first 15 cases per center. Baseline characteristics are presented in Table 1.

The median procedure time was 105 minutes (IQR 66–150), and the median fluoroscopy time was 17 minutes (IQR 10–28). A significant reduction in both procedure time (120 vs 105 minutes; $P < .001$) and fluoroscopy time (21 vs 14 minutes; $P < .001$) was observed after the 15-case learning curve (see Supplemental Table 1).

### Safety and procedural complications

Acute procedural success, defined as isolation of all targeted PVs, was achieved in 100% of cases. The VGLB system demonstrated a favorable safety profile with a low rate of major complications, as presented in Table 2. A total of 7 patients (1.6%) experienced phrenic nerve injury; of these, 6 cases (1.4%) were transient with full resolution, and 1 case (0.2%) was classified as permanent, although the patient remained asymptomatic. Nontamponade pericardial effusion occurred in 10 patients (2.3%), with none requiring intervention. There were no instances of atrioesophageal fistula, stroke, or procedure-related death.

**Table 1** Baseline and procedural characteristics of the study cohort (N = 427)

| Characteristic | Value |
|---|---|
| Patient demographics | |
| Age (y), median [IQR] | 62 [55–69] |
| Men, n (%) | 309 (72.4) |
| AF characteristics | |
| Persistent AF, n (%) | 119 (27.9) |
| History of AF (mo), median [IQR] | 24 [7–64] |
| Comorbidities and risk factors | |
| $CHA_2DS_2$-VASc score of ≥2, n (%) | 222 (52.0) |
| Hypertension, n (%) | 239 (56.0) |
| Congestive heart failure, n (%) | 48 (11.2) |
| Diabetes, n (%) | 42 (9.8) |
| Obesity (BMI of ≥30 kg/m$^2$), n (%) | 78 (18.3) |
| Moderate/severe LA enlargement, n (%) | 116 (27.1) |
| Anatomic PV variant, n (%) | 93 (21.8) |
| Procedural data | |
| Procedure time (min), median [IQR] | 105 [66–150] |
| Fluoroscopy time (min), median [IQR] | 17 [10–28] |
| % PV circumference in RAPID mode, median [IQR] | 94 [81–100] |
| Procedure in learning curve, n (%) | 135 (31.6) |

AF = atrial fibrillation; BMI = body mass index; IQR = interquartile range; LA = left atrial; PV = pulmonary vein.

## Effectiveness and freedom from arrhythmia recurrence

The overall freedom from any documented atrial tachyarrhythmia (>30 seconds) off AADs at 12 months was 73.8% (95% confidence interval [CI] 69.1–77.8). The Kaplan-Meier survival curve and its respective *P* value are shown in Figure 2.

**Table 2** Safety outcomes and procedural complications (N = 427)

| Adverse event | Number of patients | Percentage (%) |
|---|---|---|
| Device-related events | | |
| Permanent phrenic nerve palsy* | 1 | 0.2 |
| Transient phrenic nerve palsy† | 6 | 1.4 |
| Atrioesophageal fistula | 0 | 0.0 |
| Symptomatic pulmonary vein stenosis | 0 | 0.0 |
| Procedure-related events | | |
| Pericardial effusion (nontamponade)‡ | 10 | 2.3 |
| Stroke or TIA | 0 | 0.0 |
| Major vascular access complication§ | 3 | 0.7 |
| Minor vascular access complication | 2 | 0.5 |
| Death | 0 | 0.0 |

TIA = transient ischemic attack.
*Patient remained asymptomatic at follow-up.
†All cases resolved before or at the first follow-up visit.
‡None of the cases required pericardiocentesis or resulted in hemodynamic compromise.
§Defined as complications requiring surgical repair or intervention.

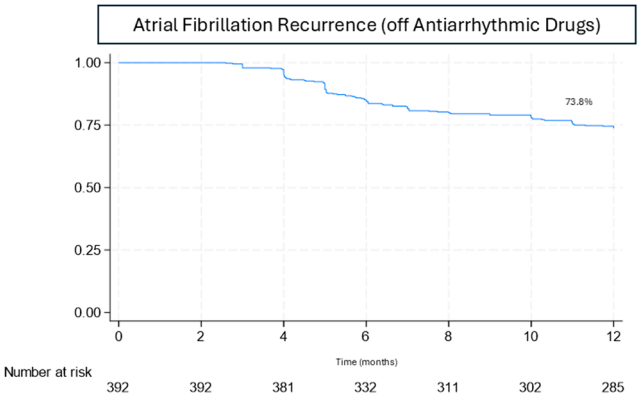


**Figure 2** Kaplan-Meier survival curve with corresponding *P* value from the log-rank test for AF recurrence endpoint after a 3-month blanking period in the overall population. AF = atrial fibrillation.

## Predictors of arrhythmia recurrence

In the unadjusted, univariate Cox regression analysis, a history of HF (hazard ratio [HR] 2.37; $P < .001$), having the procedure performed within the learning curve (HR 1.67; $P = .011$), and limited use of the RAPID mode (HR for extensive use 0.54; $P = .005$) were significantly associated with 12-month arrhythmia recurrence (Table 3). Consistently, Kaplan-Meier survival curves with log-rank testing demonstrated similar associations and also revealed that persistent AF at baseline was significantly related to AF recurrence at follow-up (Figure 3). However, in the final multivariate model that adjusted for confounding factors, only 3 variables emerged as robust, independent predictors of treatment failure (Table 4):

1. Congestive HF: the presence of HF was the strongest predictor, more than doubling the risk of recurrence (HR 2.04; 95% CI 1.16–3.57; $P = .013$).
2. Learning curve: procedures performed within the first 15 cases at a center were independently associated with a 68% higher risk of recurrence (HR 1.68; 95% CI 1.08–2.61; $P = .022$).
3. Anatomic variant: after adjustment, the presence of a PV anatomic variant was identified as a significant

**Table 3** Univariate Cox regression analysis of predictors for 12-month arrhythmia recurrence

| Variable | HR | 95% CI | *P* value |
|---|---|---|---|
| Congestive heart failure (yes vs no) | 2.37 | 1.47–3.84 | <.001 |
| Procedure in learning curve (yes vs no) | 1.67 | 1.12–2.48 | .011 |
| Extensive RAPID mode use (≥90%) | 0.54 | 0.35–0.83 | .005 |
| Anatomic variant (presence vs absence) | 1.49 | 0.97–2.30 | .067 |
| AF type (persistent vs paroxysmal) | 1.42 | 0.95–2.14 | .091 |

AF = atrial fibrillation; CI = confidence interval; HR = hazard ratio.

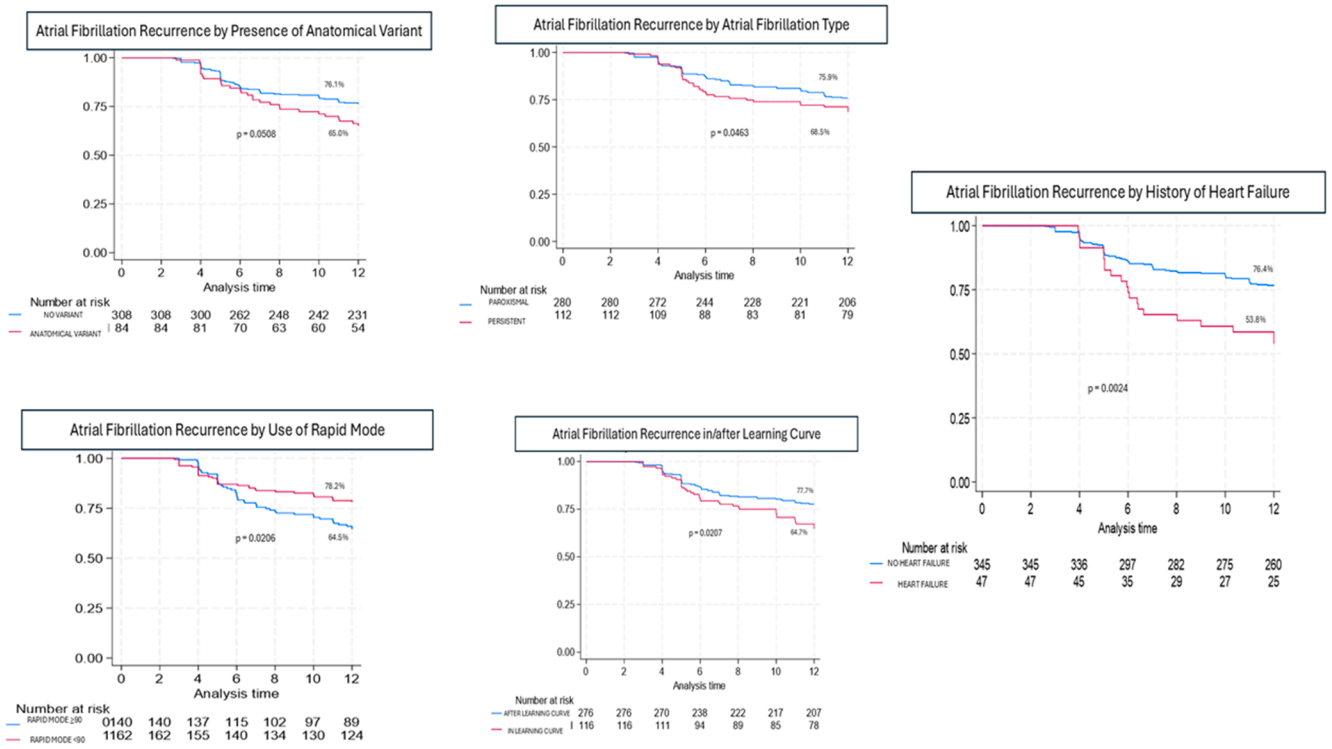


**Figure 3** Kaplan-Meier survival curve with corresponding *P* value from the log-rank test for AF recurrence endpoint after a 3-month blanking period by subgroups. AF = atrial fibrillation.

independent predictor, increasing the recurrence risk by 79% (HR 1.79; 95% CI 1.12–2.86; $P = .016$).

Notably, after adjusting for these factors, neither the type of AF (persistent vs paroxysmal) nor the extent of RAPID mode usage remained statistically significant predictors of the 12-month outcome.

## Discussion

This large, prospective, multicenter registry offers important insights into the contemporary use of third-generation VGLB ablation. First, the technology is safe and effective in a real-world setting. Second, our comprehensive analysis identified 3 independent predictors of 12-month arrhythmia recurrence: the patient's clinical substrate (HF), procedural experience (learning curve), and patient-specific anatomy (venous variants).

**Table 4** Multivariate Cox regression analysis of independent predictors for 12-month arrhythmia recurrence

| Predictor | HR | 95% CI | *P* value |
|---|---|---|---|
| Congestive heart failure (yes vs no) | 2.04 | 1.16–3.57 | .013 |
| Anatomic variant (presence vs absence) | 1.79 | 1.12–2.86 | .016 |
| Procedure in learning curve (yes vs no) | 1.68 | 1.08–2.61 | .022 |
| Extensive RAPID mode use (≥90%) | 0.67 | 0.43–1.06 | .090 |
| AF type (persistent vs paroxysmal) | 1.27 | 0.80–2.04 | .314 |

AF = atrial fibrillation; CI = confidence interval; HR = hazard ratio.

Our main finding is that the long-term success of VGLB ablation is multifactorial. The confirmation that congestive HF is a potent independent predictor of recurrence (HR 2.04) aligns with extensive literature across all ablation modalities.[15,16] HF often signifies a more advanced atrial substrate with underlying fibrosis, making PVI alone less sufficient for durable rhythm control. This reinforces the critical importance of patient selection and guideline-directed management of comorbidities.

The significant impact of the operator learning curve (HR 1.68) is a key real-world finding. Although single-shot technologies such as VGLB are designed to simplify PVI, our data clearly show that proficiency requires experience, with a curve of approximately 15 cases needed to optimize outcomes. This has direct implications for training programs and the interpretation of early results from centers adopting this technology.

Perhaps the most novel finding is the emergence of PV anatomic variants as a strong independent predictor of recurrence in the multivariate model (HR 1.79), despite its lack of significance in the initial univariate analysis. This provides

evidence that a nonstandard PV anatomy is not just a technical hurdle, but an independent risk factor for treatment failure, possibly owing to challenges in achieving complete, durable lesions around common ostia or accessory veins.

Our multivariate analysis clarifies the role of procedural automation in this context. We found that the extensive use of RAPID mode was not an independent predictor of arrhythmia-free survival, challenging the assumption that such automated features alone guarantee better clinical outcomes. The data strongly suggest that the true driver of success remains operator proficiency, with the apparent benefit of RAPID mode likely being a surrogate for the experienced hands guiding the technology. Similarly, AF type (persistent vs paroxysmal) was not an independent predictor, suggesting that, in this cohort, the presence of HF, operator inexperience, and complex anatomy were more impactful determinants of the 12-month outcome.

The overall 12-month success rate of 73.8% in the absence of AADs is a key finding of our study, given that it reflects a rigorous definition of procedural success. This outcome is competitive with other contemporary technologies. For context, the multinational survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation registry reported a comparable 12-month freedom from AF off AADs of 70.8% for PFA, whereas several other studies report higher success rates that include patients maintained on AADs.[8,9,17] Therefore, our results, particularly the 77.7% success rate achieved without AADs after the learning curve, position VGLB as a viable and effective therapeutic option.

The safety profile in our registry was favorable. The rate of permanent phrenic nerve palsy (0.2%) is a key benchmark. This rate is comparable with large cryoballoon registries (0.2%) but seems slightly higher than that reported for PFA (0.06%).[8,9,17] The complete absence of atrioesophageal fistulas in more than 400 patients is a reassuring finding for this thermal energy source.

It is important to contextualize these findings within the current landscape. Since the completion of our enrollment in 2022, PFA has rapidly gained prominence, offering an unparalleled safety profile regarding thermal injury. Our study identifies anatomic variants as a key challenge for the long-term clinical success of VGLB ablation. This presents an interesting paradox, given that the system's core feature—direct visualization—is precisely intended to help operators navigate such complexities. This may suggest that although visualization allows for a meticulous, operator-guided lesion placement, it may not fully overcome the inherent electrophysiological challenges associated with these variants, which ultimately drive arrhythmia recurrence. Therefore, the choice between a visually guided thermal approach such as VGLB and a more anatomically indifferent technology such as PFA will likely be guided by patient-specific factors, operator philosophy, institutional experience, and logistical considerations.

## Limitations

This study has several important limitations. As a nonrandomized registry, it is subject to inherent selection bias and confounding, although our multivariate analysis was designed to mitigate this. However, the potential for residual, unmeasured confounding factors remains.

Second, a portion of the initial cohort (35 of 427 patients) did not complete the 12-month follow-up and was therefore excluded from the primary effectiveness analysis. This loss to follow-up could potentially bias the effectiveness results.

We acknowledge a partial patient overlap with a previously published substudy from some participating centers focused on paroxysmal AF.[18] The present analysis is scientifically distinct because it encompasses a broader population, including both paroxysmal and persistent AF from all 9 centers, and uses a comprehensive multivariate analysis to identify independent predictors of outcome for the entire cohort.

Arrhythmia surveillance was based on a protocol of scheduled clinical visits and intermittent electrocardiographic monitoring (including 24-hour Holter), rather than continuous monitoring. This approach, although comprehensive, is known to underestimate the true burden of asymptomatic AF recurrence, and thus, our reported effectiveness rates may represent an overestimation

Finally, the 12-month follow-up period, although providing valuable midterm data, does not allow for conclusions regarding the very long-term durability of PVI with this technology.

## Conclusion

In this large, multicenter, real-world registry, third-generation VGLB ablation demonstrated a favorable safety and effectiveness profile for the treatment of AF. The procedure was associated with a low rate of major complications. The 12-month effectiveness, defined as freedom from arrhythmia recurrence off AADs, was 73.8% for the overall cohort. Importantly, this rate increased to 77.7% for procedures performed after the initial operator learning curve, highlighting the technology's potential in experienced hands.

Our analysis also identified 3 key independent predictors of arrhythmia recurrence: congestive HF, procedures performed within the learning curve, and the presence of PV anatomic variants. A key finding is that a patient's underlying anatomy is an independent determinant of success, even after accounting for operator experience. This underscores that, beyond the choice of technology, a successful outcome is critically dependent on 3 domains: patient selection (clinical substrate), operator proficiency, and patient-specific anatomic factors. These findings provide clinicians with real-world data to better stratify risk, manage expectations, and make more informed therapeutic decisions in the evolving landscape of AF ablation.

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**Authorship:** All authors attest they meet the current ICMJE criteria for authorship.

**Patient Consent:** All patients provided a written informed consent.

**Ethics Statement:** The study was conducted in accordance with the Declaration of Helsinki and received approval from the local ethics committees at all participating sites.

# Appendix

## Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hroo.2025.09.004.

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