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Operator learning curve with a novel dual-energy lattice-tip ablation system

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ABSTRACT

BACKGROUND The SPHERE Per-AF trial demonstrated noninferiority for a primary composite effectiveness endpoint in patients with persistent atrial fibrillation (AF) treated with a 9-mm, lattice-tip, pulsed field (PF)/radiofrequency (RF) system (74%) vs conventional contact force-sensing RF (65%). Although operators were highly experienced with the control, the vast majority was new to the investigational system.

OBJECTIVE The aim of this study was to assess the learning curve using this novel system.

METHODS Patients were grouped based on the sequential procedures performed per operator. Operators who performed $\leq$2 investigational procedures were excluded. The composite effectiveness endpoint was freedom from acute procedural failure, repeat ablation at any time, recurrence of arrhythmia, drug initiation/escalation, or cardioversion each at 1 year excluding a 3-month blanking period. Efficiency endpoints included "skin-to-skin" procedure time.

RESULTS The total cohort included 443 patients (235 investigational [31 roll-in], 208 control). Primary effectiveness in the investigational cohort improved significantly with increased procedural order. Efficacy was 65% (74 of 114) for the first 5 patients per operator, 75% (33 of 44) for patients 6 to 10, and 80% (60 of 75) for patients >10. Kaplan-Meier effectiveness estimates at 1-year follow-up were significantly higher in the investigational cohort after 10 procedures performed, compared with control (80% vs 65%, $P < .05$). With the investigational system, total procedure time was reduced by 25 minutes (100 vs 125) within the first 5 procedures performed ($P < .001$).

CONCLUSION AF ablation with a novel dual-energy, lattice-tip ablation system resulted in greater clinical efficacy compared with conventional RF after a rapid operator learning curve, with superior procedural efficiency noted from the initial procedures onward.

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Clinical implications

The novel dual-energy, wide-footprint ablation and mapping system allows for enhanced efficacy and efficiency after a short operator learning curve in patients with persistent atrial fibrillation, a population that has historically experienced suboptimal clinical outcomes.

Introduction

The prevalence of atrial fibrillation (AF) worldwide is growing dramatically as the population ages.[1] Historically, AF catheter ablation has been reserved as a second-line therapy after failure of pharmacologic therapy. Based largely on contemporary trials demonstrating efficacy superiority of AF ablation across spectrums of AF classification (paroxysmal to long-standing persistent)[2–4] and varied patient populations,[5–7] recent consensus guidelines have endorsed first-line AF ablation.[8,9] Thus, with an expanding population eligible for AF ablation, there is a need for enhanced procedural efficiency without compromising safety or efficacy. Whereas AF ablation delivery has historically been thermal, either heating via radiofrequency (RF) or cooling via cryoballoon (CBA), in recent years, pulsed field (PF) ablation has provided a novel, nonthermal method of delivery that appears to have reduced thermal complications while increasing procedural efficiency.[10–13]

Recently, the SPHERE Per-AF (Treatment of Persistent Atrial Fibrillation with Sphere-9 and Affera Mapping and Ablation System) randomized clinical trial evaluated a novel dual-energy (PF + RF), lattice-tip catheter with a compatible ablation and mapping system against a well-established RF ablation and mapping system. The investigational arm demonstrated noninferiority for the primary effectiveness and safety endpoints and superiority for procedural efficiency metrics.[14] Effectiveness was 73.5% in the investigational vs 65.2% in the control arm. The safety profile was similarly low in both arms, with primary safety events in 3 (1.4%) patients in the investigational arm and in 2 (1.0%) patients in the control arm (none were device-related). The novel lattice-tip ablation catheter (Sphere-9, Medtronic, Dublin, Ireland) possesses key features that differ from conventional point-by-point RF catheters. These include a larger footprint, a compressible catheter tip (9 mm), the ability to both map and ablate, and the flexibility to create wide-area focal ablation lesions using either RF or PF energy in less time than conventional RF catheters.[14,15] In this current post hoc analysis of the SPHERE Per-AF trial, the operator learning curve is evaluated for this novel, dual-energy, lattice-tip catheter; the primary effectiveness endpoints and procedural efficiency were analyzed as a function of operators' sequential procedural order. Operators of the investigational and control catheters in the SPHERE Per-AF trial were all experienced users of the control ablation catheter and mapping system.

Abbreviations

AF: atrial fibrillation

PF: pulsed field

PVI: pulmonary vein isolation

RF: radiofrequency

Methods

Study design

The primary endpoints of the SPHERE Per-AF trial (NCT05120193) have been previously published.[14] In brief, this pivotal, multicenter, randomized, single-blind, controlled trial was designed to test noninferiority endpoints of safety, effectiveness, and efficiency when comparing a novel dual-energy lattice-tip catheter (Sphere-9 catheter) with a compatible ablation and mapping system (Affera Mapping and Ablation System, Medtronic) to the conventional contact-force sensing RF point-by-point ablation system (Thermocool Smarttouch SF, Biosense Webster, Irvine, CA) with electroanatomic mapping (CARTO 3, Biosense Webster). The data examined (herein) evaluated the operator learning curve and outcomes with this novel ablation and mapping system.

Procedural interventions

All procedures required high-density mapping to be performed with each respective mapping system. The ablation protocol required wide-area circumferential pulmonary vein isolation (PVI) using RF and PF ablation with the investigational device and RF ablation with the control device. Confirmation of acute entrance block was performed after a 20-minute waiting period or through provocative testing. Other linear ablations were permitted to treat documented atrial tachycardias at the physician's discretion. Standard of care procedures (established at each center) were used for procedural strategies including transseptal puncture, esophageal management, fluoroscopy use, and intracardiac echocardiography. All patients signed informed consent forms before any activities in the study. Data collection adhered to the principles outlined in the Declaration of Helsinki (revision 2013) and Good Clinical Practices. The study was approved by local institutional review boards and ethics committees at each center.

Analysis cohort and endpoint definitions

Each participating center was allowed to treat up to 2 roll-in patients to familiarize themselves with the investigational mapping and ablation system. The learning curve analysis included the full investigational cohort, including roll-in patients. Patients were grouped based on the sequential investigational procedures performed by each operator during the trial; patients in group 1: first 5 patients treated with the investigational system by each operator, group 2: sixth to tenth patient for each operator, group 3: patients treated by operators who had previously performed >10 procedures with the investigational device. A total of 56 experienced operators who were accustomed to the RF control catheter and system participated in the trial, of whom 47 performed investigational procedures and 47 performed control procedures. The number of procedures performed by each operator varied. Operators who performed $\leq$2 procedures using the investigational system (15 operators) were excluded from the analysis in the investigational cohort. When 2 operators were reported for 1 procedure, the procedure was attributed to the operator with the highest enrollment of patients treated with the investigational system in the trial to prevent duplicate observations in the dataset. One additional operator was excluded because of attribution of all their patients to the second operator in the respective procedures. A flow diagram showing patient inclusion/exclusion can be found in Figure 1. The composite effectiveness endpoint was freedom from acute procedural failure, repeat ablation at any time, recurrence of arrhythmia, antiarrhythmic drug initiation/escalation, or cardioversion each at 1 year excluding a 3-month blanking period. Procedural efficiency endpoints included total procedural time (defined as "skin-to-skin" time) and PVI time (defined as time from first to last lesion applied to isolate the pulmonary veins only).

Statistical summary

Quantitative variables were summarized using standard descriptive statistics, including number of nonmissing observations, mean and standard deviation, and were compared using a Student *t* test or Wilcoxon rank sum test. Categorical variables were summarized using classical frequency statistics: number of nonmissing observations, frequency and percentage by category, and compared among groups by using a χ^2 test or the Fisher exact test. Kaplan-Meier analysis of the freedom from primary effectiveness failure events was performed along with the log-rank test. Statistical analyses were performed using the SAS version 9.4 software package (SAS Institute, Cary, NC).

Results

The total cohort for this analysis included 443 patients. Of those, a total of 235 patients were treated with the investigational device (204 randomized patients + 31 roll-in patients), and 208 patients were treated with the control device. Baseline characteristics of the sample are presented in Table 1.

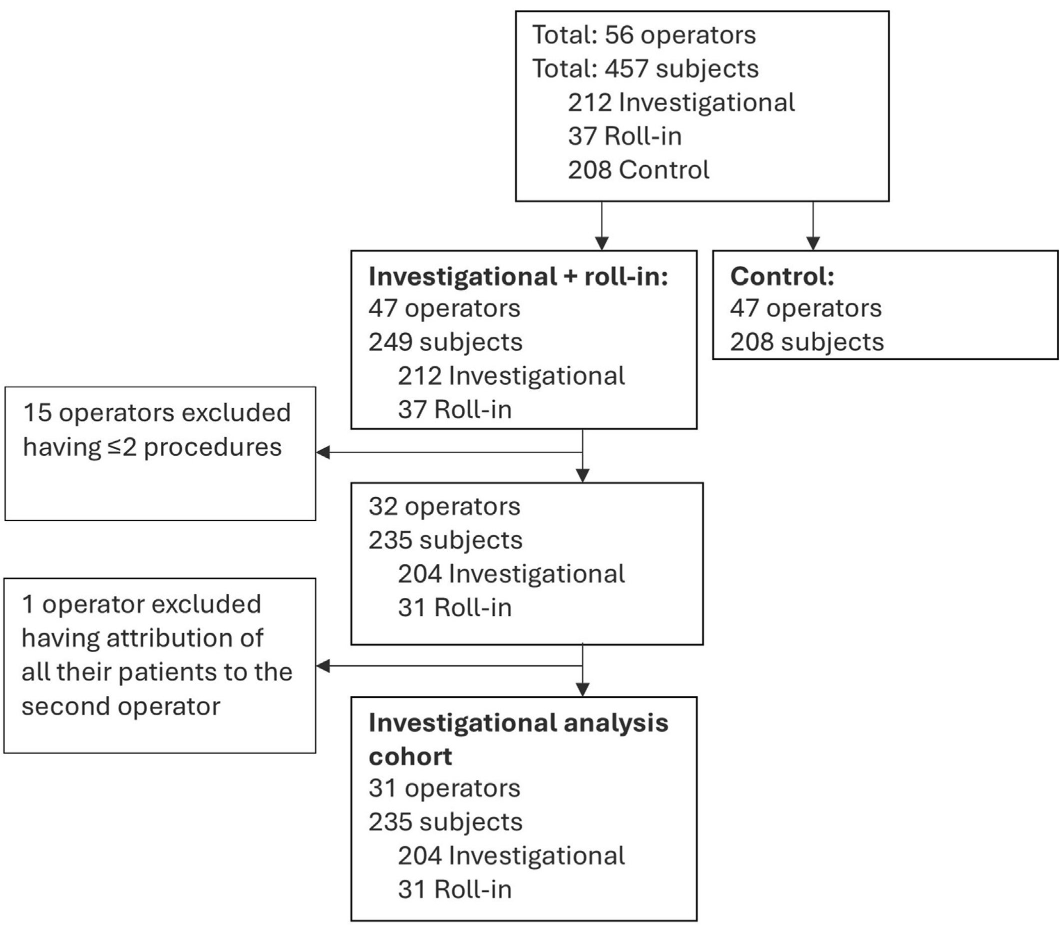

Figure 1
Flow diagram.

Table 1 Patient baseline characteristics

Baseline characteristics	Investigational cohort (N = 235)	Control cohort (N = 208)
Age (years)	67.9 ± 8.2	66.7 ± 8.8
Female sex	76 (32.3%)	61 (29.3%)
Time from first persistent AF diagnosis (years)	1.3 ± 2.6	1.3 ± 2.2
BMI (kg/m^2)	30.2 ± 4.8	30.3 ± 4.9*
Left atrial diameter (mm)	43.4 ± 6.1†	44.0 ± 5.4
LVEF (%)	57.4 ± 7.2	55.5 ± 8.0
CHA_2DS_2-VASC Score	2.4 ± 1.3	2.3 ± 1.4‡
Number of failed Class I or III AADs	1.1 ± 0.4§	1.1 ± 0.4¶
History of electrical cardioversion	163 (69.4%)	140 (67.3%)
History of atrial flutter	39 (16.6%)	36 (17.3%)
History of atrial tachycardia	6 (2.6%)	2 (1.0%)
Congestive heart failure	40 (17.0%)	26 (12.5%)
Coronary artery disease	43 (18.3%)	35 (16.8%)
Myocardial infarction	10 (4.3%)	7 (3.4%)
Hypertension	177 (75.3%)	157 (75.5%)
Cardiomyopathy	24 (10.2%)	14 (6.7%)
Stroke/TIA	14 (6.0%)	11 (5.3%)
COPD	16 (6.8%)	13 (6.3%)
Diabetes	42 (17.9%)	34 (16.3%)
OSA	54 (23.0%)	57 (27.4%)
Renal disease	23 (9.8%)	15 (7.2%)

AADs = antiarrhythmic drugs; AF = atrial fibrillation; BMI = body mass index; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; OSA = obstructive sleep apnea; TIA = transient ischemic attack.
*BMI available for 207 of 208 control patients.
†Left atrial diameter available in 233 of 235 investigational patients.
‡CHA_2DS_2-VASC score available in 207 of 208 control patients.
§Number of failed Class I or III AADs available in 224 of 235 investigational patients.
¶Number of failed Class I or III AADs available in 192 of 208 control patients.

Primary effectiveness increased with increased procedural order (Figure 2A). The primary success rate was 65% (74 of 114 patients) in investigational group 1 (first 5 patients treated by N = 31 operators). Increased procedural experience with the investigational system brought about higher primary effectiveness, including 75% (33 of 44 patients) in group 2 (sixth through tenth patient treated by N = 10 operators) and 80% (60 of 75 patients) in group 3 (patients beyond the tenth treated by N = 8 operators). The Kaplan-Meier estimate for primary effectiveness was significantly higher in investigational group 3 (80%) vs the overall effectiveness in the control group (65%, $P < 0.05$; Figure 2B). The rate of pulmonary vein first pass isolation (per vein) was 321 of 325 (98.8%) for the investigational group 1, 133 of 133 (100%) for group 2, and 282 of 287 (98.3%) for group 3 ($P = .34$ between groups). In the control group, first-pass isolation was significantly lower (552 of 583 [94.7%]) compared with the overall investigational group (680 of 687 [99.0%]; $P < .001$).

A total of 5 primary safety events occurred in the operator learning curve analysis cohort. With the investigational system, three primary safety events happened within group 1 (procedures 1 to 5): during an operator's sequential procedure #2 (hemoptysis with no signs of active bleeding by endoscopy and no recurrence), another operator's procedure #2 (hospitalizations for pulmonary edema due to hypertensive urgency), and procedure #5 (exacerbation of chronic obstructive pulmonary disease). No events occurred in group 2 (procedures 6 to 10) and group 3 (>10) in the investigational group, and there was no statistical difference in safety among the 3 groups (group 1 vs 2 vs 3). With the control system, events occurred in group 1 and group 2 (operators' procedures #1 and #10: 2 hospitalizations because of pulmonary edema).

Compared with control procedure times (125 [89,155] minutes), significantly lower total procedure times were observed in the first 5 investigational procedures (group 1: 100 [85,120] minutes, $P < .0001$), and maintained throughout subsequent investigational procedures in the trial ($P < .0001$, Figure 3A). In addition, the time required to achieve PVI was already significantly shorter in the first 5 investigational

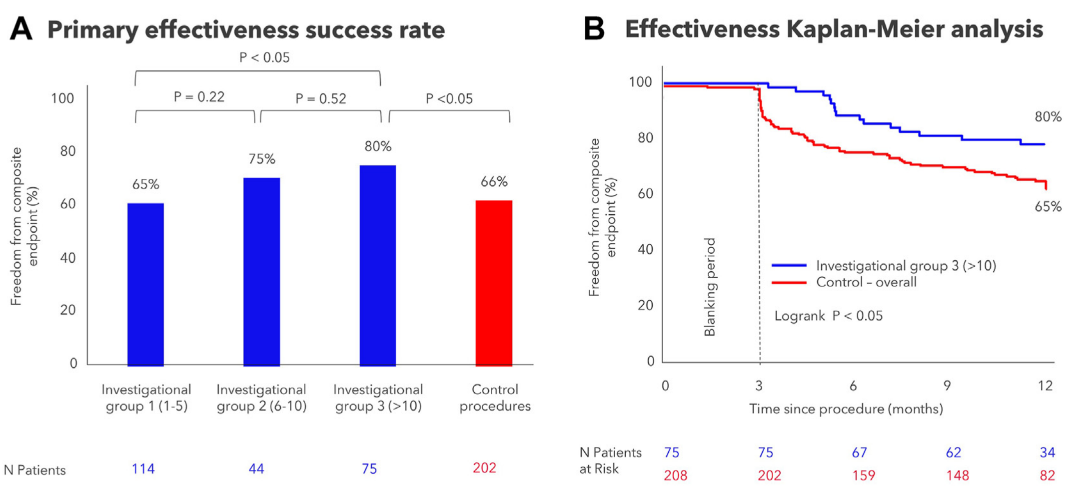

Figure 2
Primary effectiveness after operator learning curve. **A:** Primary effectiveness success rate with increased procedural order (group 1: procedure 1 to 5, group 2: procedures 6 to 10, and group 3: more than 10 procedures) in the investigational arm (*blue*) compared with the overall success rate in the control arm (*red*). **B:** Kaplan-Meier curve of freedom from primary effectiveness endpoint in patients in the interventional cohort treated after >10 procedures (*blue*) compared with all patients in the control cohort (*red*).

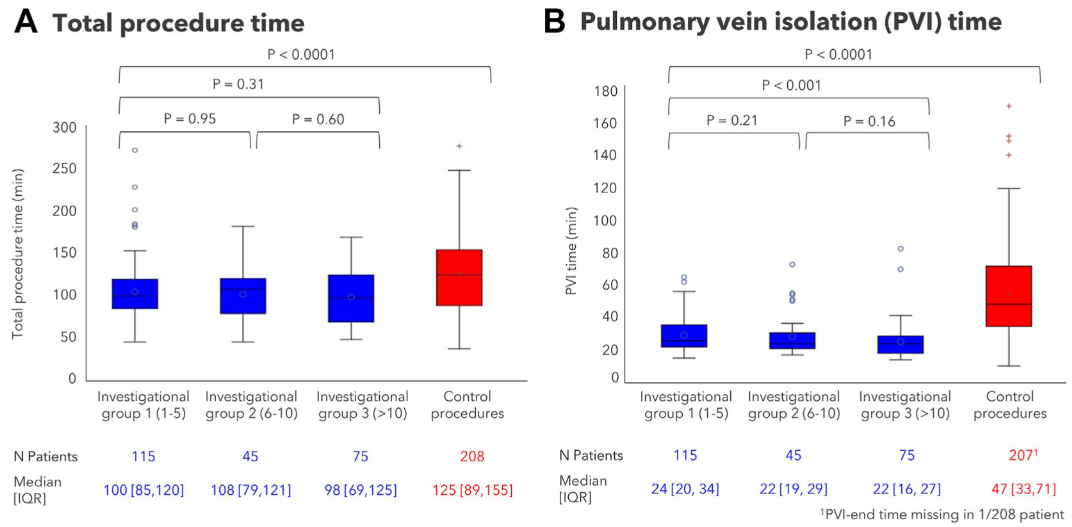

Figure 3
Procedural efficiency after operator learning curve. **A:** Total procedure time (defined as "skin-to-skin" procedure time), and (**B**) pulmonary vein isolation (PVI) time (defined as "time from first to last PVI lesion") with increased procedural order (group 1: procedure 1 to 5, group 2: procedures 6 to 10, and group 3: more than 10 procedures) in the investigational cohort (*blue*) compared with the control cohort (*red*).

patients (group 1: 24 [20,34] minutes) compared with overall PVI time in the control group (47 [33,71] minutes, $P < .0001$), and PVI time then improved from investigational group 1 (1 to 5 procedures) to group 3 (>10 procedures) with a median reduction of 2 min (8%, $P < .001$; Figure 3B).

The learning curve of the operators with the most investigational procedures was assessed separately to validate the results with the full investigational cohort (Figure 4). Three operators performed >20 procedures each in the trial: 2 operators performed 27 procedures each and 1 operator performed 26 procedures. The primary effectiveness success rate among these 3 operators followed a similar operator learning curve compared with the full investigational cohort; 67% in investigational patient group 1 (first 5 patients), 73% in investigational group 2 (patients 6 through 10), and 80% in investigational group 3 (after having performed 10 procedures). PVI time for these 3 operators also decreased with increased procedural order. PVI time improved a median of 4 minutes (14%) from investigational patient group 1 to group 2, and 6 minutes (21%) from group 1 to group 3 ($P < .01$).

Discussion

This post hoc secondary analysis of the SPHERE Per-AF trial examined the efficacy and efficiency implications of the operator learning curve within the investigational arm (lattice-tip

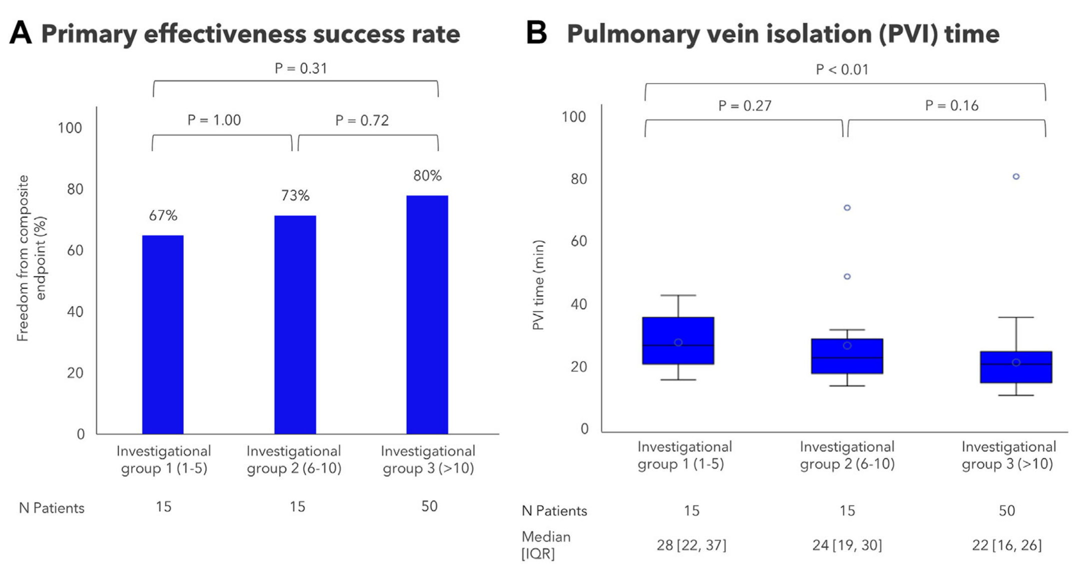

Figure 4
Learning curve in 3 operators performing >20 procedures. Assessment of learning curve with increased procedural order (group 1: procedure 1 to 5, group 2: procedures 6 to 10, and group 3: more than 10 procedures) in 3 operators who performed more than 20 investigational procedures in the trial. **A:** Primary effectiveness endpoint success rate and (**B**) time to achieve pulmonary vein isolation time (PVI), using the investigational system.

mapping/ablation catheter and compatible mapping system) of this randomized controlled trial. From an efficacy perspective, enhanced clinical effectiveness was observed with additional cases performed with a significant trend after 10 investigational procedures performed per operator. For operator sequential procedures >10, an 80% 12-month effectiveness endpoint was observed compared with 65% in the control RF arm ($P < .05$). From an efficiency perspective, total procedural skin-to-skin time was 25 minutes shorter than the control RF arm (100 vs 125 minutes, $P < .001$), even during operators' first procedures, with similar skin-to-skin times observed thereafter with additional procedures.

In the SPHERE Per-AF trial, all the proceduralists were experienced focal operators with the control RF catheter and mapping system. Although there are certainly novel features of the Sphere-9 catheter compared with the control RF catheter (lattice-tip design with wide tissue footprint, toggling between PF/RF energy, mapping, and ablation) and differences among the respective mapping systems, the investigational procedure remains at its core a focal ablation approach, albeit with the larger footprint catheter (9 mm vs 3.5 mm). As such, the rapid efficiency improvements observed in the investigational arm even with operators' first procedures likely reflects a comfortable and smooth transition from RF via a similar procedural workflow but with the added ability to ablate more myocardial territory in less time. In clinical practice, the total skin-to-skin time reduction may be even more marked than observed in the trial for several reasons. First, in the investigational arm, although a reduction in PVI times was observed, there was a mandated waiting period before post-PVI testing (entrance block) that was often longer in the investigational arm. Second, in the investigational arm, there was a higher percentage of procedures with non-PVI lesions performed than in the control RF arm (96% vs 86%)[14]; in effect, more atrial tissue was ablated in less time. Notably, many study operators also believed that visualization of the investigational Sphere-9 catheter was excellent with intracardiac echocardiography (ICE). Thus, with integrated catheter visualization within the Affera mapping system, for operators accustomed to a low-fluoroscopy or fluoroscopy-free workflow with the control RF catheter, a rapid and seamless transition to a similar workflow was observed with the investigational Sphere-9 catheter.

From an effectiveness perspective, although still fundamentally a focal ablation approach, there are distinct differences between the investigational Sphere-9 and control RF catheter that likely led to operator optimization over time. First, the compressible lattice-tip design of the Sphere-9 catheter provides a safe tissue–catheter interaction; indeed, no cardiac tamponade or perforation was observed in the trial.[14] In addition, instead of a quantitative contact force sensor, the Sphere-9 catheter uses multiple local impedance indicators displayed on the mapping system to inform an operator regarding catheter tip-to-tissue proximity. Although current PF literature suggests the presence of catheter–tissue contact/proximity is more important than quantitative contact force,[16–18] the same is not true with RF. This methodologic difference in operator assessment of the catheter–tissue interface between the investigational and control catheters is one of the largest workflow variances and thus is likely to account in part for the observed 10-procedure efficacy learning curve.

PF has emerged as a growing alternative energy modality for AF ablation, as evidenced by recent volume increases and market approval of this new technology in the catheter ablation space. However, there is little published on operator learning curves. What published data do exist are largely related to the pentaspline PF ablation catheter, which is designed primarily as an over-the-wire, single-shot device for PVI, as opposed to a focal ablation catheter. In the 5S study,[19] procedural characteristics were compared among patients performed during validation (cases 1 to 25) and streamline (cases >25) phases. Streamline cases had significantly shorter total procedural times (8-minute reduction) and higher rates of index single-shot PV isolation (11% absolute increase). In the ATHENA registry of the pentaspline catheter,[13] efficiency improvements (total procedure and PVI time) were noted after 10 operator cases, with further efficiency improvements observed after >20 cases. Procedural times were significantly shorter between both previous RF and CBA operators. In the EU-PORIA (European Real-World Outcomes With Pulsed Field Ablation in Patients With Symptomatic Atrial Fibrillation) Registry,[12] although case-by-case operator learning curves were not reported, significantly shorter total procedural times were noted among previous CBA operators compared with point-by-point RF operators, thought attributable to a similar over-the-wire, single-shot procedural technique. Arrhythmia-free survival at 1 year, however, was independent of operator experience or primary previous energy modality, although more pericardial tamponade was observed in previous point-by-point RF operators. Freedom from recurrence of arrhythmia at 1 year was 66% in the persistent AF population. In our review, none of the available registries report case-by-case operator effectiveness learning curve data.

In the SPHERE Per-AF trial, rapid efficiency improvements were observed compared with the RF control arm already in the operators' first cases. In addition, the SPHERE Per-AF trial showed an excellent safety profile, with high long-term efficacy accomplished in a persistent AF patient population after a short, 10-procedure efficacy learning curve.

Study limitations

The study limitations within the SPHERE Per-AF trial have been previously reported.[5] In brief, those previously disclosed limitations included the lack of continuous invasive arrhythmia monitoring. In this analysis, effectiveness and efficiency endpoints were used as surrogate markers for a learning curve or endpoint, which is only suggestive as to when mastery of a novel technology is achieved. Moreover, the "learning curve" data are defined within the confines of a randomized clinical trial, whereas "learning" within a commercial setting may differ because of manufacturer and peer-to-peer training or implementation of established physician/facility best practices. This analysis was not prespecified, and the number of patients treated by each operator varied, resulting in a decrease in contributing operators with increasing procedural order. However, sensitivity analyses in operators that performed >20 procedures resulted in a comparable operator learning curve, which justifies the use of all operators with >2 procedures performed in the trial. Also, it is possible that changes in the patient population have occurred over time, especially given the small numbers and changing operators, which influenced outcomes. However, patient enrollment in SPHERE Per-AF occurred over a period of 12 months in total, suggesting some stability in common use and standard of care. Further, this study represents high-volume centers and operators, particularly those experienced with focal RF ablation. Consequently, a learning curve was not expected in the RF control arm, as the operators were well experienced with the control ablation system. This establishment of mastery in the RF control arm was confirmed by the analyses in Supplemental Figures 1 to 3, that assessed efficiency and efficacy parameters based on the procedural order of RF control procedures in the trial. Ultimately, more evidence is needed for real-world experience and perhaps generalizability to predominant CBA operators.

Conclusion

Within the SPHERE Per-AF trial, there was a rapid and well-defined learning curve for the novel dual-energy, lattice-tip catheter with compatible ablation and mapping system. The effectiveness of the interventional system was more pronounced compared with conventional RF after a short operator learning curve of 10 procedures, with high procedural efficiency achieved already during the first 5 procedures.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2025.02.006.

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