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ORIGINAL ARTICLE

5S Study: Safe and Simple Single Shot Pulmonary Vein Isolation With Pulsed Field Ablation Using Sedation

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BACKGROUND: Pulsed field ablation represents an energy source specific for ablation of cardiac arrhythmias including atrial fibrillation. The aim of the study was to describe the adoption and the process of streamlining procedures with a new ablation technology.

METHODS: All-comer atrial fibrillation patients (n=191; mean age 69±12 years) underwent catheter ablation with a pulsed field ablation ablation device exclusively using analog-sedation. In the validation phase (n=25), device electrogram quality was compared with a circular mapping catheter to assess pulmonary vein isolation and esophageal temperature monitoring was used. In the streamline phase (n=166), a single-catheter approach was implemented. Postprocedural cerebral magnetic resonance imaging was performed in 53 patients. In 52 patients, esophageal endoscopy was performed at day 1 after the procedure. Follow-up was performed using 72 hours Holter ECGs.

RESULTS: On a pulmonary vein basis, pulmonary vein isolation rate was 100% including a single shot isolation rate of 99.5%. The electrogram information of the pulsed field ablation catheter and the circular mapping catheter were 100% congruent. Neither esophageal temperature rises nor esophageal thermal injury were observed. Two minor strokes occurred, presumable due to air embolism during catheter exchanges through the large bore sheath (13.8 F ID). In the streamline phase, reduced procedure times (46±14 versus 38±13 minutes, *P*=0.004), no further strokes and a low incidence of silent cerebral injury (10/53 patients; 19%) were noted. During short-term follow-up, 17/191 patients (9%) had a atrial tachyarrhythmia recurrence.

CONCLUSIONS: The pulsed field ablation device allows for simple and safe simple single shot pulmonary vein isolation using standard sedation protocols. Procedural speed and efficacy are remarkable and streamlining measures have added safety.

Key Words: atrial fibrillation ■ catheter ■ cell death ■ electroporation ■ myocardium ■ pulmonary vein

Nonstandard Abbreviations and Acronyms

AF	atrial fibrillation
LA	left atrium
LSPV	left superior PV
MRI	magnetic resonance imaging
PFA	pulsed field ablation
PN	phrenic nerve
PV	pulmonary vein
PVI	pulmonary vein isolation

WHAT IS KNOWN?

- Pulsed field ablation demonstrated promising results in preclinical and early feasibility studies.
- Little data for commercial clinical use have been reported.

WHAT THE STUDY ADDS

- A simple single catheter mapping and ablation approach—The 5 S strategy—with a novel pulsed field ablation device for pulmonary vein isolation was demonstrated to be feasible.
- The study adds further evidence on the safety and efficacy of pulsed field ablation in a broader patient population.

Pulsed field ablation (PFA) is a new ablation technology for cardiac arrhythmias.[1] Lesion formation is achieved by applying rapidly alternating high electrical fields to cardiac tissue leading to nanopore formation (also referred to as electroporation) in cardiac cells and subsequently cell death. Unlike, contemporary energy sources PFA creates cell injury in a nonthermal fashion. Myocardium is characterized by a high susceptibility towards PFA in comparison to surrounding tissue. Altogether, this opens a broad therapeutic window composed of high efficacy (myocardial damage) and low safety concerns (little to no collateral damage). The so-called PFA tissue selectivity was confirmed in preclinical and clinical studies showing low vulnerability of nerves, vasculature, and esophageal tissue to PFA.[2–5]

To date, early clinical investigations focus on atrial fibrillation (AF) ablation. First in human studies report, favorable procedural data as well as excellent data on lesion durability in terms of durable pulmonary vein (PV) isolation (PVI).[6–8]

The first device that obtained official approval in Europe was the Farapulse PFA ablation system (Farapulse, Menlo Park, CA). It consists of a 12 F over-the wire ablation catheter (FARAWAVE) that is inserted into the left atrium (LA) via a 13.8 F steerable sheath (FARADRIVE). High voltage electrical fields (1.8–2.0 kV) are created by the generator (FARASTAR).

This study sought to describe the adoption and the process of streamlining of a new ablation technology in a high volume AF ablation center with the goal to assess safety, reproducibility, and efficacy.

METHODS

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

The study was approved by the institutional review board. The study complies with the declaration of Helsinki. Patients had to sign the patient informed consent form before enrollment. The study device is CE marked.

Patient Population

All comer patients with symptomatic AF refractory to the treatment of at least one antiarrhythmic drug including beta blockers (class I–III) scheduled for ablation were eligible to enter the study. Patients had to be 18 to 85 years old. No echocardiographic exclusion criteria were applied.

Patients were excluded if they had had previous PVI attempt or were ineligible for treatment with oral anticoagulation. Moreover, presence of an intracardiac thrombus, moderate, or severe mitral valve disease led to exclusion from the study. Preprocedural imaging such as magnetic resonance imaging (MRI) or CT to assess PV anatomy was not performed.

Preablation Protocol

To exclude intracardiac thrombi and to assess potential mitral valve disease, preprocedural transesophageal echocardiography was performed in patients with a CHA_2DS_2-VaSc score ≥2 or presenting in AF at the day of the procedure. Oral anticoagulation was continued until the morning of the procedure and resumed on the evening after the intervention.

Investigational Device

The FARAWAVE ablation catheter consists of 5 splines with each spline carrying 4 electrodes. The outermost electrodes may be used for electrogram recording and pacing. Two catheter sizes with a maximal diameter of 31 or 35 mm were available. The ablation device was introduced into the LA via a steerable sheath (13.8 F inner diameter; FARADRIVE) and was navigated over-the-wire to the desired ablation area. The support wire is of particular importance to achieve both an optimal alignment with the course of the target PV as well as a stable position at the PV ostia. Preferably, a 0.035″ guidewire with a 1 cm straight tip (Amplatz Extra Stiff, Cook Medical, Bloomington, IN) was used.

Of note, using the pull-wire mechanism integrated in the catheter handle, the catheter configuration can be changed seamlessly into different poses. It can be adjusted to a basket-like or a flower-like pose, when partially or fully expanded, respectively (Figure 1). For extra PV ablation sites, the support wire may be retracted to allow direct contact of the catheter tip and the flower pose with atrial tissue.

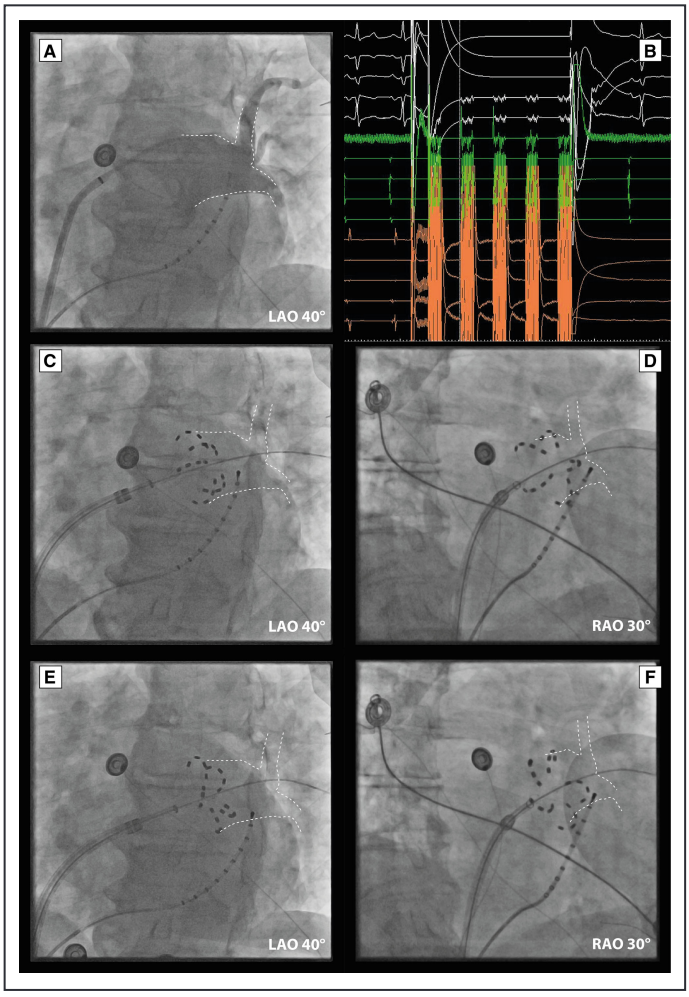

Figure 1. **Positioning and ablation of FARAWAVE at the left inferior pulmonary vein (LIPV). A**, Selective angiogram of a large LIPV in a 40° left anterior oblique (LAO) projection. **B**, Electrograms during the first energy application at the LIPV. The first 4 leads reflect the surface ECG. Below, electrograms from the coronary sinus catheter (green) and the FARAWAVE at the LIPV (orange) are displayed. Please note, the abolition of PV potentials after the first train of impulses, for example, single shot PV isolation (PVI). **C**, Positioning a 35 mm FARAWAVE over a guidewire in a basket pose at the LIPV ostium in left anterior oblique (LAO) 40°. **D**, Corresponding fluoroscopic image in a 30° right anterior oblique (RAO) angulation. **E**, Positioning a 35 mm FARAWAVE over a guidewire in a flower pose at the LIPV ostium in LAO 40°. **F**, Corresponding fluoroscopic image in a 30° RAO angulation.

For ablation, the generator (FARASTAR) charges numerous capacitors to generate an electrical voltage of 1.8 to 2.0 kV. After confirmation of an appropriate catheter position, the ablation can be initiated via the graphic user interface at the console. Energy applications are delivered as a biphasic waveform in a microseconds scale unsynchronized to cardiac rhythm.[7] A train of 5 consecutive waveforms is delivered accounting for a total of 2.5 seconds ablation time. Based on initial clinical experience, PV ablation was performed with pairs of energy applications. That is, at each PV one pair of applications was performed in a basket configuration, then the basket was rotated ≈36° to change spline orientation before another pair of applications was delivered. The same algorithm was repeated using the flower configuration (Figures 1 and 2). In summary, 8 energy applications were delivered at each PV. In case a left common PV was present, operators adhered to the same workflow and 4 pairs of pulses were delivered to both subbranches. Exceptionally, left common PVs with a long common trunk were treated with a single 4×2 PFA application set.

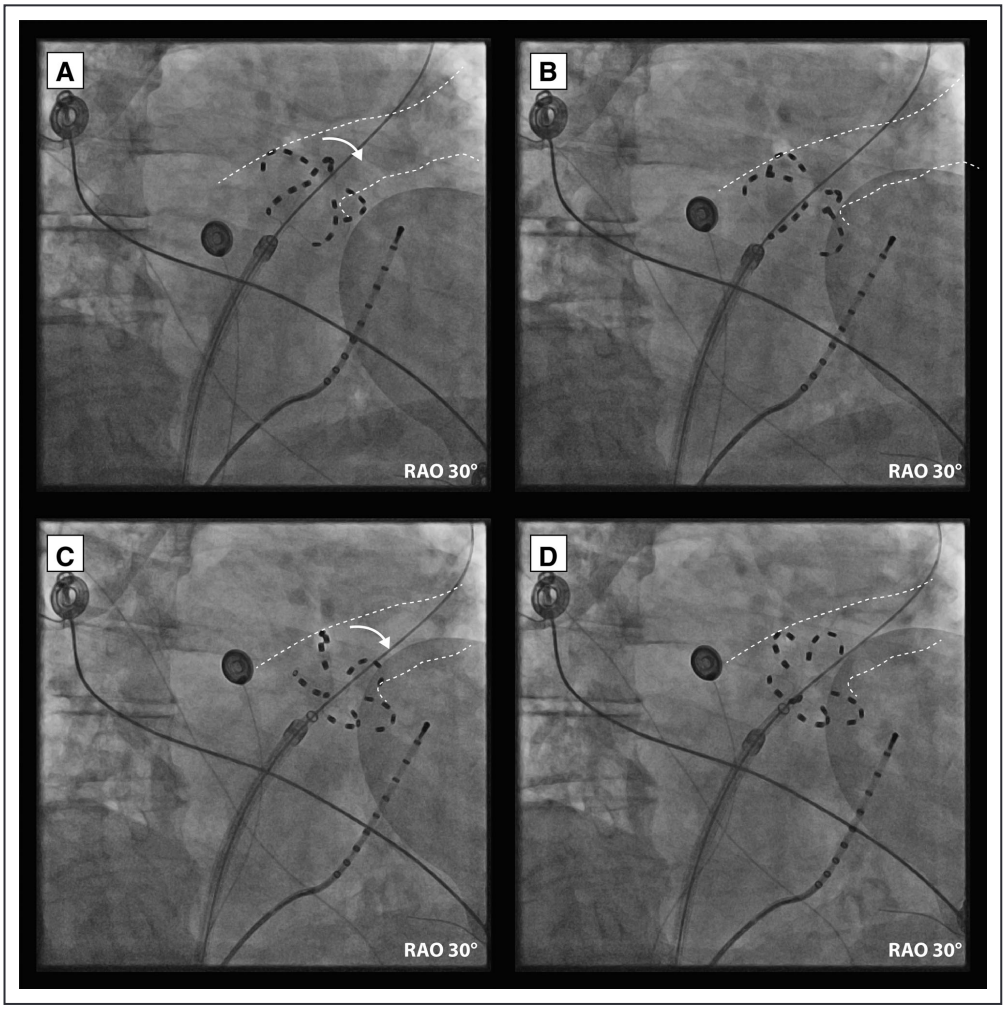

Figure 2. Ablation using pairs of pulsed field ablation (PFA) pulses in different poses and catheter reorientation. The FARAWAVE is located at the left superior pulmonary vein (PV) and shown in a right anterior oblique (RAO) 30° projection. In the 2 **upper** parts the catheter is in a basket pose. Re-orientation of splines is accomplished by simple rotation after the first pair of pulses before a second set of pulses is applied. The **lower** parts show the FARAWAVE in 2 different flower poses to apply another 2 pairs of PFA pulses.

Ablation Procedure

All ablations were performed under intravenous sedation using propofol, midazolam, and fentanyl according to a German positional paper.[9] After femoral venous access, intravenous heparin was administered to maintain an activated clotting time ≥300 seconds. Then, a decapolar diagnostic catheter was placed in the coronary sinus. Single transseptal puncture was performed using a 8-Fr sheath and a Brockenbrough needle with fluoroscopy guidance. A 7 F-multipurpose catheter was used to acquire selective PV angiographies in standard angulations (right anterior oblique 30°/left anterior oblique 40°).

The transseptal sheath was then exchanged for the FARADRIVE sheath using a guidewire in the left superior PV (LSPV). The sheath was continuously flushed with heparinized saline at 20 cc/min. Device size selection (31 versus 35 mm FARAWAVE) was left at the discretion of the operator. PFA ablation started in the LSPV and was performed in a clockwise fashion (LSPV, left inferior PV, right inferior PV, and right superior, Video S1).

In case of bradycardia <40/min during the energy deployments, the steerable diagnostic catheter was repositioned from the coronary sinus into the right ventricle to allow back-up pacing (VVI 40/min). No atropine was administered to identify ablation induced bradycardia events.

Validation Phase

In a validation phase, electrogram recordings using the FARAWAVE were compared with the standard circular mapping catheter to assess procedural end point of PVI.

Therefore, in the initial 25 cases preablation and postablation electrical mapping of PV potentials and the LA was performed using both a circular mapping catheter (circular mapping catheter, Biosense Webster, 15 mm) and the FARAWAVE ablation catheter to compare the quality of intracardiac electrogram recordings. A circular PV mapping catheter was introduced and PV baseline recordings based on the angiograms obtained. In case of normal sinus rhythm, pacing from the coronary sinus was performed to discern PV spike from LA far-field electrograms (Figure 3).

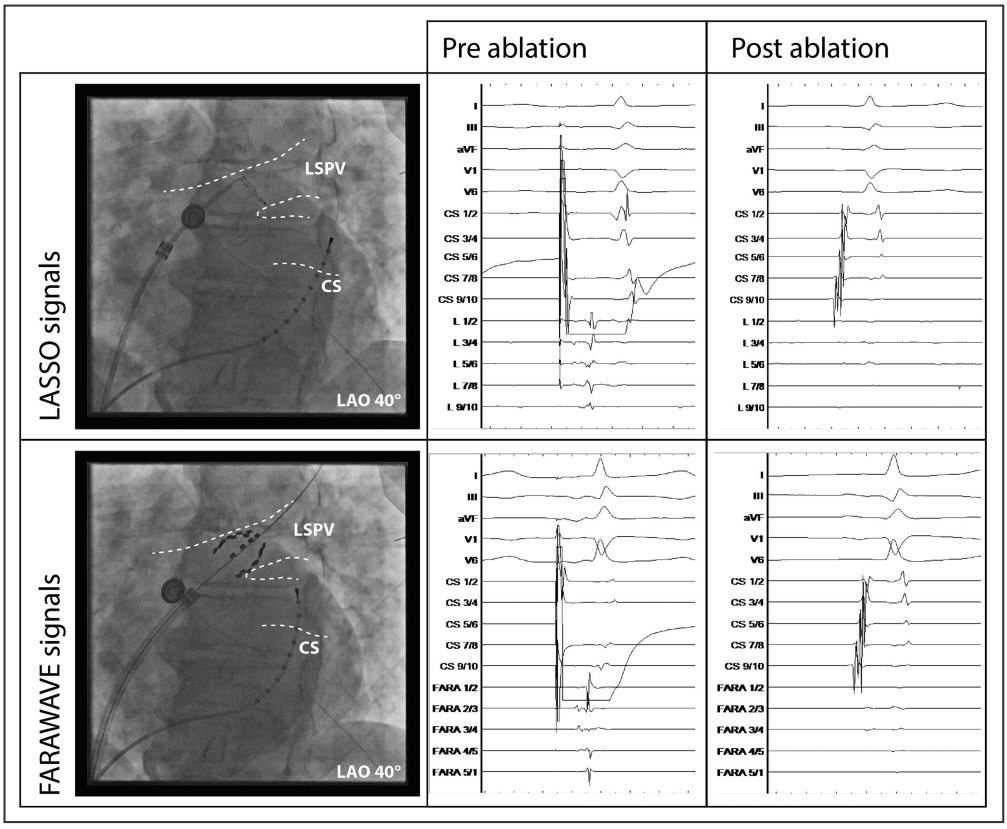

Figure 3. Validation of electrograms. In the **upper** parts an example of a spiral mapping catheter recording from the left superior pulmonary vein (LSPV) is depicted. **Left**, Fluoroscopic view of the spiral mapping catheter in the LSPV in a LAO 40° angulation. **Middle**, Intracardiac electrograms during pacing from a multipolar catheter in the coronary sinus (CS). Upper tracings show the surface ECG. CS: Intracardiac electrograms from the CS. L: Intracardiac electrograms from the spiral mapping catheter. **Right**: After ablation at the LSPV. Note, the absence of the PV potential in the L recordings. **Lower left**: Fluoroscopic view of the FARAWAVE catheter in the LSPV in a LAO 40° angulation. **Middle** and **lower** part correspond to the **upper** part. RAO indicates right anterior oblique.

The FARAWAVE catheter was introduced to the LA over a guidewire. Careful air evacuation of the sheath and sheath handle was performed to minimize bubble entrapment between the catheter splines. After having entered the LA, the FARAWAVE catheter was deployed at the LSPV in a basket pose at the similar level as the circular mapping catheter to record baseline PV potentials.

After the first and the last energy application at each PV, the catheter was deployed at the PV ostium in a basket pose to assess PVI and compared with the recordings of the circular mapping catheter.

Esophageal temperature monitoring was performed during ablation using a commercial temperature probe (SensiTherm, Abbott) in the initial validation phase.

Streamline Phase

In the streamline phase, all procedural steps remained unchanged but to streamline work flow and to reduce catheter exchanges through the FARADRIVE sheath the use of the circular mapping catheter was omitted and esophageal temperature monitoring was abandoned. Moreover, ablation voltage was increased to 2.0 kV as a standard setting. Single-shot PVI was defined as abolition of the PV spike after the first energy application at the respective PV

Postprocedural Care

All patients underwent postinterventional transthoracic echocardiography to exclude pericardial effusion. Therapeutic anticoagulation was continued or resumed the evening after the procedure. Before discharge, a 24-hour Holter ECG was obtained to exclude early arrhythmia recurrence. All previously ineffective antiarrhythmic drugs were halted immediately after the procedure.

Esophageal Endoscopy

In a subset of patients (n=52), endoscopy was performed the day after the ablation to exclude thermal esophageal injury.

Cerebral Imaging

In a subset of patients (n=53), a cerebral diffusion-weighted MRI was acquired using 1.5 to 3.0 Tesla scanners between 24 and 48 hours after the ablation as previously described.[10] An axial T2 weighted turbospin echo sequence with the following parameters was obtained: slice thickness 5 mm, repetition/echo time 4000/100 ms, flip angle 150°, matrix 448×512. Second, an axial fluid-attenuated inversion recovery sequence was acquired with the following parameters: slice thickness 5 mm, repetition/echo time/inversion time 9000/104/2500 ms, flip angle 150°, matrix 416×512. Then, an axial and a coronal echo planar imaging sequence (diffusion-weighted sequence) was acquired with the following parameters: slice thickness, 5 mm; repetition/echo time, 4600/19 and 5500/119 ms; flip angle, 90; matrix, 128×128. Any focal hyperintense area in the diffusion-weighted MRI images with the corresponding hypo-intensity in the apparent diffusion coefficient map was defined as SCL. Images were adjudicated by 2 independent radiologists blinded to the patient's clinical symptoms. For each patient, the number, size, and location of lesions were assessed. The size was classified into 3 categories (0–5, >5–10, >10 mm).

Follow-Up

All antiarrhythmic drugs had to be stopped immediately after the procedure. All patients attended outpatient clinic visits including 72-hour Holter-ECG at 3 months. In case of symptoms suggestive of an arrhythmia recurrence, 24-hour Holter-ECGs were performed or patients received an external event monitor. A recurrence was defined as any documented atrial tachyarrhythmia episode lasting >30 seconds.

RESULTS

Between March and August 2021, 200 patients with paroxysmal (n=127; 64%) or persistent (n=73; 36%) AF were included into the study. Nine patients were excluded from the analysis because more complex ablation including extra PV sites was performed, thus interfering with comparability between groups. Patient characteristics were summarized in Table 1. Patients were 69 ± 12 years old, 42% were female and the vast majority of patients was overweight (mean body mass index, 28±5).

Table 1. Patient Characteristics (Table view)

Patient characteristics, n=191	
Age, y	69±12
Gender	
Male, %	58% (111)
Female, %	42% (80)
BMI, n	28±5
Type of AF	
Paroxysmal, %	62% (119)
Persistent, %	38% (72)
Hypertension, %	67% (128)
Coronary artery disease, %	12% (22)
Heart failure, %	9% (17)
Diabetes, %	14% (26)
History of stroke, %	5% (9)
Left atrial diameter, mm	42±7
Left ventricular ejection fraction, %	60±10
Failed antiarrhythmic drugs	
Class I, %	7% (13)
Class III, %	12% (22)

Values are given in mean±SD unless otherwise indicated. AF indicates atrial fibrillation; and BMI, body mass index.

Procedural Data

Procedures were performed at equal distribution by 6 experienced electrophysiologists.

All PVs (100%) were isolated exclusively using the PFA device (Table 2). Single-shot isolation, for example, PVI with the first energy application, was achieved in 744/748 (99.5%) PVs including 16 left common PVs. Overall, single-shot isolation for all PVs in an individual patient was achieved in 187 (98%) patients. In total, a mean of 32±1 applications were delivered for each patient.

Table 2. Procedural Characteristics (Table view)

Procedural characteristics, n	Phase 1	Phase 2	*P* value	Overall
	25 Pts, 98 PV	166 Pts, 650 PVs		191 Pts, 748 PVs
Duration of overall procedure, mins				
Mean±SD, n	46±14	38±14	0.004*	39±14
Median (min–max)	43 (28–92)	35 (19–90)		36 (19–92)
Overall fluoroscopy time, mins				
Mean±SD, n	11±5	8±4	0.001*	9±4
Median (min–max)	9.9 (5.1–22.9)	7.5 (3.9–27.9)		7.7 (3.9–27.9)
Number of catheters used				
1, n (%)	24 (96%)	166 (100%)		190 (99.5%)
2, n (%)	1 (4%)	0 (0%)		1 (0.5%)
Catheter size (31/35 mm), n (%)	14/11 (56%/44%)	82/84 (49%/51%)		96/95 (50%/50%)
Number of veins attempted, n	98	650	…	748
Number of applications, per vein	8±1	8±0		8±1
Single-shot isolation, n (%)	95 (97%)	649 (100%)	0.007†	744 (99.5%)

Procedural characteristics, n	Phase 1	Phase 2	*P* value	Overall
	25 Pts, 98 PV	166 Pts, 650 PVs		191 Pts, 748 PVs
Patients with all PVs single-shot isolation, n (%)	22 (88%)	165 (99%)	0.006†	187 (98%)

PVs indicates pulmonary veins.

* The *P* values refer to the mean and were calculated with Student *t* test.

† The *P* values were calculated with Fisher exact test.

The average procedure and fluoroscopy time were 39±14 and 9±4 minutes. A statistically significant shorter procedure time was observed in the streamline phase compared with the validation phase (46±14 versus 38±14 minutes, *P*=0.004). Figure 4 illustrates the evolution of skin-to-skin procedure times and ablation times during the course of the study.

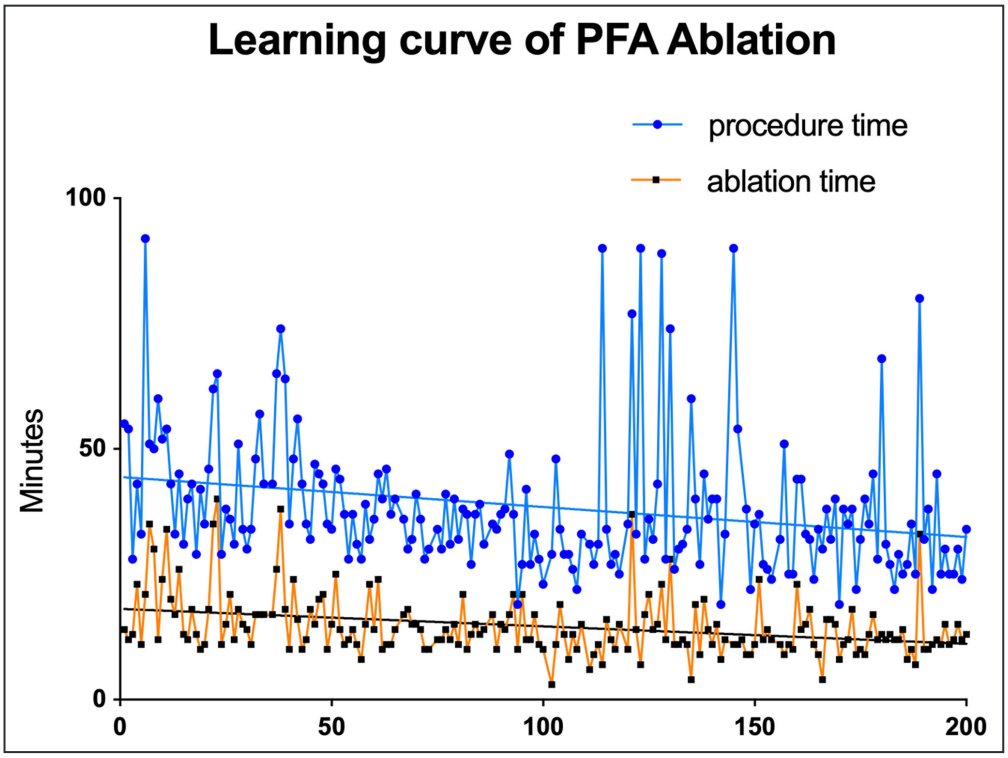

Figure 4. Procedure and ablation time during the study course. The **upper** part depicts the evolution of procedure (blue) and ablation (orange) time. Please, note the slope of the procedure time is steeper than the slope of the ablation time indicating the effects of the streamline process on the procedure.

During the validation phase (n=25 pts) acute PV isolation indicated by the FARAWAVE basket configuration (n=175 PVs: entrance block in sinus rhythm and coronary sinus pacing) was always confirmed using the circular mapping catheter comparing preablation and postablation PV potentials. Of note, in 96 and 95 procedures, the 31 or the 35 mm device were used, respectively.

Autonomic Response and PN Capture

Bradycardia response following PFA for PVI was a common observation. In total, 118/200 (62%) patients required RV pacing. PFA related bradycardia was more common while ablation at left sided PVs. According to our series, the rank order of bradycardia events was (LSPV > left inferior PV > right superior PV > right inferior PV). This phenomenon was not linked to the size and configuration of the Farawave catheter.

Phrenic nerve (PN) capture resulting in diaphragmatic contractions was a typical observation during PFA and was observed in 166/191 (87%) and 118/191 (62%) patients at the right and left sided PVs, respectively.

In ≈80% of patients, mild to moderate coughing was observed when PFA was delivered at the LPVs. Procedural work-flow remained unaffected.

Sedation

In all 191 patients, deep sedation was successfully accomplished. A total of 4.9±0.9 mg midazolam, 61±19 µg fentanyl, and 360±36 mg propofol was administered. Neither a switch to general anesthesia nor mechanical ventilation was required.

Periprocedural Complications

In the initial validating phase, 2 strokes have been observed (Table 3). The first was diagnosed in patient No. 11 by blurred vision 12 hours after the procedure. Using computed tomography, intracerebral hemorrhage was excluded. MRI scans proved a novel ischemic lesion in the posterior circulation. All active clotting time levels were therapeutic (>300 s) during the uneventful procedure at all times. After 4 weeks, loss of vision had normalized.

Table 3. Procedural Complications (Table view)

	Validation phase, n=25	Streamline phase, n=166	*P* value	Overall, n=191
Pericardial effusion	0	1 (0.6%)		1 (0.5%)
Stroke	2	0	0.361	2 (1%)
Transient phrenic nerve palsy	1 (4%)	1 (0.6%)	1.000	2 (1%)
Vascular access complication	2 (8.0%)	2 (1.2%)	0.361	4 (2.1%)
Thermal esophageal injury	0/25	0/27		0
Silent cerebral injury	N/A	10/53 (19%)		10/53 (19%)

All *P* values were calculated with Fisher exact test. N/A indicates data not collected.

The second patient (No. 16) presented with weakness of the right hand as well as gait ataxia the morning after the procedure. In the MRI, multiple small acute cerebral lesions were detected in the basal ganglia as well as in the cerebellum. The latter was the largest at 13×17 mm. During the clinical follow-up visit at 3 months, symptoms had completely resolved.

In one patient (No. 189), cardiac perforation with pericardial effusion requiring pericardiocentesis was observed. After reversal of anticoagulation with protamine bleeding stopped and no further action was required. The patient was discharged 2 days after the procedure.

In 2 patients, a transient right sided PN palsy with a loss of diaphragmatic contraction was noted instantaneously after PFA at the right superior PV. PN function recovered within <1 minute. Using fluoroscopy, intact PN function was confirmed the next day.

In 4 patients, major groin hematoma without vascular laceration were observed. Management was conservative.

Esophageal Endoscopy

In 52/191 patients, esophageal endoscopy was performed within 48 hours after the ablation. In none (0/52) of these patients, endoscopic signs of thermal injury were observed.

Cerebral MRI

In the streamline phase, 53 patients diffusion weighted MRI was performed within 24 hours after the ablation. Acute asymptomatic cerebral injury was present in 10 patients (19%). None of the patients presented with neurological deficits.

Follow-Up

As of now, 119/191 and 69/191 patients have completed the 3 and 6 months follow-up visit, respectively. Of these, 13/119 (11%) and 4/69 patients (5.8%) had experienced a symptomatic documented ATa recurrence after a single procedure off antiarrhythmic drugs.

Repeat Mapping

Five patients underwent a repeat procedure, of whom 4 patients had experienced a symptomatic ATa recurrence and one patient was scheduled for a left atrial appendage closure procedure. The time from the index procedure was 86±22 days. Of 20 PVs that were re-mapped, 2 showed LA-PV re-conduction. Both lateral PVs exhibited small conduction gaps at the anterior ostium in a single patient.

DISCUSSION

This article summarizes initial clinical experience using the Farapulse PFA system and proposes a streamlined AF ablation workflow in the so far largest nonselected, all-comer AF patient cohort. This novel catheter ablation system allows to deploy PFA in 2 different catheter configurations resulting in (1) 100% acute PVI rate and a 99.5% single-shot PVI rate including the full learning curve of 6 EP operators along with (2) very short intervention times. Most importantly, (3) after streamlining, the procedure exhibit a favorable safety profile without evidence for damage to neighboring tissues confirming previous animal and human PFA data. (4) Intracardiac basket catheter electrograms are sufficient to correctly identify PVI. Therefore, our streamlined workflow appears to eliminate the need for post-PFA catheter exchanges to confirm PVI and hence increases procedural safety.

Safety

Catheter ablation has evolved to a safe intervention as illustrated by the large CABANA trial (Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation) reporting a 6.9% complication rate.[11] Thermal ablation modalities, however, may cause injury in neighboring tissues leading to disabling (eg, PN injury), life threatening (eg, cardiac tamponade), or deleterious complications (atrio-esophageal fistula).

Therefore, there is a continuing need to optimize the safety of AF ablation. The advent of PFA has been associated with certain hopes for increased safety due its nonthermal ablation effects and specific cardiomyocyte selectivity. In preclinical studies, no thermal injury, whatsoever, was observed at the above mentioned tissues.[1,2,4,12] In the present clinical study, a stepwise safety evaluation was applied.

At first, esophageal temperature monitoring and postprocedural endoscopy were performed in 52 patients and neither showing relevant temperature rises nor any evidence for post-PFA thermal mucosal changes. Although, atrio-esophageal fistula is a very rare phenomenon after AF ablation and may still not be fully excluded with PFA current data is at least reassuring and in line with a smaller series.[13]

Single-shot devices like balloons are associated with a low but relevant incidence of PN injury.[14,15] In this series, diaphragmatic contractions during energy applications were very common, but we did not observe a persistent diaphragmatic weakening indicative of PN injury.

This is compatible with preclinical data demonstrating preserved nerve fascicles within zones of fibrosis after PFA treatment.[16]

In our series, we observed 2 patients with a stroke in the validation phase. While the source of embolism remains unclear, improper sheath handling appeared to be the most likely cause of air embolism. The validation phase represented the beginning of our learning curve and despite careful sheath management air embolism linked to catheter exchanges through the lumen of the 16.8 FARADRIVE sheath cannot be excluded. This highlights the need for careful de-airing large bore sheaths, in particular after insertion of any catheter. Earlier studies using the cryoballoon elegantly demonstrated that catheter exchanges constitute one of the most prominent causes for air embolism in this setting.[17] During the course of the study, additional catheter exchanges such as the circular mapping catheter were abandoned and mapping as well as ablation were performed with a single device. This contributed to a favorable safety profile as confirmed by the absence of any further clinical events as well as a low incidence of asymptomatic cerebral lesions in the MRI sub-study. In earlier studies, asymptomatic cerebral lesions were detected at similar rates in our center.[10,18]

In addition, one could consider to perform catheter exchanges while submerging the sheath handle to further reduce the risk for air embolism. The transparent FARADRIVE sheath allows to detect air bubbles on visual inspection and contributes to a favorable risk management.

Simplicity

During the course of the study, various actions were taken to streamline the procedure. Aside from a single diagnostic catheter, PVI can be achieved and confirmed exclusively using the FARAWAVE catheter. In 100 PVs, preablation and postablation spiral catheter PV recordings served as the internal benchmark to define PVI. In all PVs, preablation and postablation recordings were compared with PV basket electrograms demonstrating 100% congruent findings. This was accompanied by a decrease in both ablation and procedure time. Of note, the relative reduction of the pure ablation time was smaller (−17% versus −24% comparing Q3 versus Q1). thus confirming that abandoning the re-mapping and establishing standard maneuvers facilitated the procedure rather than the ablation itself. In comparison to competitor devices such as the irrigated RF balloon, the cryoballoon or the laser balloon this further simplifies the PVI procedure.

Of note, no preprocedural imaging was used to exclude particular anatomic variants. The unique sizing options including a seamless change from a basket to the maximal device diameter in the so-called flower configuration (31 mm or 35 mm) allow for successful PVI across many different PV anatomies including long common trunks in an unselected all-comer AF patient population. Of note, this catheter allows different diameter configurations without transition and can be used almost like a size-adjustable device.

Moreover, safety measures to prevent collateral damage such as esophageal temperature monitoring or PN pacing still recommend for thermal balloon ablation may be waived in clinical routine. Thus, operators already experienced with PVI may be capable to adopt all required maneuvers with FARAWAVE in a short period of time.

Of note, all procedures have been performed using a standard sedation protocol. Despite of muscular and diaphragmatic contractions general anesthesia was never required.

Single-Shot PV Isolation

In the group of single-shot devices, PFA seems to most reliably achieve single-shot isolation. In our series in 779/783 PVs (99.5%) acute PVI was obtained after a single PFA application. Of note,

in all 4 instances, a different, less-supportive guidewire was used. All remaining PVs were isolated after a second series of PFA after repositioning using modified catheter configuration in flower and basket shapes. Importantly, no catheter exchange using a different devices size was or switch to a different energy source was required. In reference, experienced centers report single shot and single mapping isolation rates of 86% and 91.6% with the cryoballoon and laser balloon, respectively.[19,20]

Versatility

Beyond PVI, the PFA catheter may be used for substrate based ablation as demonstrated for posterior left atrial wall isolation.[21] In this series, mapping and ablation of left atrial macrorentrant tachycardias involving the mitral isthmus were successfully performed in selected cases. However, larger series seem to be required to fully understand the merits and demerits of PFA for these indications.

Very recently, the first clinical ablation of premature ventricular contractions from the right ventricular outflow tract was also described.[22]

Limitations

This is a nonrandomized real world series in 200 all-comers AF patients undergoing first PFA ablation in Germany using the sizeable FARAWAVE device. While this cohort is certainly still too small to draw definite conclusions, the present data is encouraging with regards to procedural safety at neighboring organs. Moreover, the mid- and long-term clinical course need to be carefully assessed to analyze both safety and efficacy.

It needs to be pointed out, that the reported workflow in particular preprocedural TEE imaging and intraprocedural PV angiographies may differ from other center's practice and may affect the results.

Conclusions

The novel PFA device allows for simple and safe simple single shot PVI using standard sedation protocols in a nonselected all comer AF population. Procedural speed and efficacy are remarkable and streamlining measures have added safety. Long-term follow-up data is required.

ARTICLE INFORMATION

Supplemental Material

Video S1

ARTICLE INFORMATION

Received December 17, 2021; accepted May 13, 2022; published online May 26, 2022.

Supplemental Material is available at https://www.ahajournals.org/doi/suppl/10.1161/CIRCEP.121.010817.

For Sources of Funding and Disclosures, see page 372.

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