The durability of pulmonary vein isolation using the visually guided laser balloon catheter: Multicenter results of pulmonary vein remapping studies

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BACKGROUND The visually guided laser ablation (VGLA) catheter is a compliant, variable-diameter balloon that delivers laser energy around the pulmonary vein (PV) ostium under real-time endoscopic visualization. While acute PV isolation has been shown to be feasible, limited data exist regarding the durability of isolation.

OBJECTIVE We sought to determine the durability of PV isolation following ablation using the balloon-based VGLA catheter.

METHODS The VGLA catheter was evaluated in patients with paroxysmal atrial fibrillation (3 sites, 10 operators). Following transseptal puncture, the VGLA catheter was advanced through a 12-F deflectable sheath and inflated at the target PV ostium. Under endoscopic guidance, the 30° aiming arc was maneuvered around the PV and laser energy was delivered to ablate tissue in a contiguous/overlapping manner. At ~3 months, all patients returned for a PV remapping procedure.

RESULTS In 56 patients, 202 of 206 PVs (98%) were acutely isolated. At 105 ± 44 (mean ± SD) days, 52 patients returned for PV remapping at which time 162 of 189 PVs (86%) remained isolated and 32 of 52 patients (62%) had all PVs still isolated. On comparing the operators performing <10 vs ≥10 procedures, the durable PV isolation rate and the percentage of patients with all PVs isolated were found to be 73% vs 89% ($P = .011$) and 57% vs 66% ($P = .746$), respectively. After 2 procedures and 12.0 ± 1.9 months of follow-up, the drug-free rate of freedom from atrial fibrillation was 71.2%.

CONCLUSIONS In this multicenter, multioperator experience, VGLA resulted in a very high rate of durable PV isolation with a clinical efficacy similar to that of radiofrequency ablation.

KEYWORDS Atrial fibrillation; Ablation; Laser; Paroxysmal; Pulmonary veins; Endoscopic visualization

ABBREVIATIONS **AF** = atrial fibrillation; **PV** = pulmonary vein; **VGLA** = visually guided laser ablation

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Introduction

Pulmonary vein (PV) isolation is the mainstay of catheter-based therapy for patients with drug refractory, paroxysmal atrial fibrillation (AF).[1–4] Although acute isolation of the PVs can be achieved in virtually all cases, chronic clinical efficacy is limited by a high rate of electrical reconnections.[5–12] This may, in part, be due to the difficulty in manipulating an ablation catheter around the PVs and delivering contiguous and transmural lesions.

Recently, a balloon-based visually guided laser ablation (VGLA) catheter has been designed to facilitate PV isolation.[13–17] The VGLA catheter has (1) real-time endoscopic visualization, (2) a maneuverable aiming arc, and (3) laser energy that is delivered at the site of the aiming arc to ablate tissue. The first-generation balloon was noncompliant and had a large 90−120° aiming/ablative arc. This often resulted in a suboptimal area of balloon/tissue contact, and the large ablative arc limited energy delivery because of concerns of thrombus formation from ablation in areas with overlapping blood.[13] The second-generation VGLA catheter has a compliant balloon with an expandable variable diameter that was designed to accommodate PVs with varied anatomies and sizes. This new balloon together with a smaller 30° aiming/ablative arc was intended to improve the

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area of balloon/tissue contact and allow more optimal energy delivery.

With adequate lesion overlap, we and others have demonstrated in both preclinical and clinical cases that it is possible to place circumferential and contiguous lesions, which ultimately translated to a high rate of acute PV isolation.[14–17] In addition, in a small, single-center clinical experience, we demonstrated that this translated to durable PV isolation when patients were routinely remapped 3 months after the index ablation procedure.[14] In order to determine the generalizability of this observation, we now report on the multicenter, multioperator experience of the durability of PV isolation achieved by using the VGLA catheter, as assessed by PV remapping procedures at 3 months postablation.

Methods

The study consisted of 56 patients enrolled in 2 European studies at 3 clinical sites: (1) Homolka Hospital, Prague, Czech Republic; (2) Institute for Clinical and Experimental Medicine, Prague, Czech Republic; and (3) San Camillo-Forlanini Hospital, Catholic University of Sacred Heart, Rome, Italy. A total of 10 primary operators participated in these procedures. The studies were approved by the human ethics committees at the participating institutions. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the article as written.

The balloon-based VGLA system

The components of the ablation system (CardioFocus, Inc, Marlborough, MA) were previously described in detail.[14] The components of the system are (1) a variable-diameter, compliant balloon catheter (ie, the VGLA catheter), (2) a deflectable 12-F inner-diameter sheath, and (3) the console. The VGLA catheter connects to the console and is delivered through the deflectable sheath. The catheter has a central shaft with a soft, atraumatic tip. Within the central shaft of the balloon catheter are multiple lumens for circulating D_2O to cool the balloon, an optical fiber that is used to generate a maneuverable 30^o arc of light for aiming and ablation, and a 2-F endoscope. A diode laser (980 nm) is used to ablate tissue.

The VGLA catheter is delivered through the 12-F deflectable sheath and is positioned and inflated at the PV ostium. The compliant balloon can be inflated to multiple pressures to change its size so that balloon/tissue contact is maximized regardless of the size and shape of the target PV ostium. The 2-F endoscope provides real-time endoscopic visualization, with blood appearing red and the area of tissue in contact with the balloon appearing white. The endoscopic view is partially obscured in the area behind the central shaft. The balloon catheter has a radiopaque "L" marker (subsequently changed to a "Z") on the shaft that is located 180^o opposite to the location of the partially obscured view on the endoscope. Thus, the fluoroscopic and endoscopic images can be correlated to identify anterior, posterior, superior, and inferior directions. The aiming arc can be retracted/advanced and rotated along the surface of the balloon to deliver laser energy at desired sites.

Patient selection and study design

This article includes data from 2 open-label, nonrandomized clinical studies. The inclusion criteria for the studies were slightly different but in general were broad. The key inclusion criteria were as follows: age 18−75 years and recurrent, symptomatic paroxysmal AF. Antiarrhythmic drug failure was not a prerequisite for the first study, while the second study accepted patients who had failed any class I–IV drug. Common exclusion criteria included the following: left atrial diameter >5 cm, left ventricular ejection fraction <30%, prior cardiac ablation, presence of intracardiac thrombus, moderate or severe valvular heart disease, myocardial infarction or cardiac surgery within the prior 3 months, and stroke or transient ischemic attack in the prior 6 months. One study excluded PV diameter >30 mm, and the other excluded PV diameters >32 mm. For oval PVs, the sum of the major and minor dimensions was divided by 2 and used as the PV diameter. Baseline echocardiograms were not required in 1 protocol. In both protocols, cardiac computed tomography scans were performed at baseline and again at 3 months postablation.

Following the procedures, antiarrhythmic drug was used at the discretion of the physicians; all patients were typically taken off antiarrhythmic drugs immediately postprocedure. However, they sometimes were restarted on these prior to the 3-month remapping procedures for clinical recurrences. Patients were discharged on warfarin or low-molecular-weight heparin until the international normalized ratio was ≥2.0. All patients returned at 3 months for a second procedure regardless of intervening symptomatology. Therefore, we are able to report on chronic PV isolation rates in addition to acute results. As the primary objective was to assess for persistent PV isolation at 3 months, clinical data were not routinely collected in this blanking period. After the 3-month remapping procedure, clinical follow-up was continued for 12 months in all patients. The follow-up methods were variable and dependent on the treating physician. Follow-up included clinic visits at 3- or 6-month intervals and either Holter or transtelephonic monitoring at variable intervals.

Ablation and remapping procedures

All procedures were performed under conscious sedation. For the index ablation procedure, 2 transseptal punctures were performed: one for the 12-F inner-diameter deflectable sheath and VGLA catheter and the other for a circular mapping catheter. Heparin was given as intravenous boluses and constant infusion to maintain an activated clotting time of >300 seconds. Baseline PV electrograms were recorded by using fluoroscopy via the circular mapping catheter that was positioned at the vein ostium. The VGLA catheter was advanced through the deflectable sheath and positioned at the PV ostium. The balloon was inflated to a sufficient

Table 1 Initial ablation procedure data

	N = 56
PV isolated, n (%)	202 of 206 (98.1%)
Mean number of attempts to isolate per PV	1.3
Fluoroscopy time, mean ± SD (range) (min)	23 ± 15 (7−85)
Ablation lesions per patient, mean ± SD	143 ± 33
Ablation time, mean ± SD (range) (min)	113 ± 38 (46−221)
Laser time, mean ± SD (range) (min)	64 ± 15 (37−110)
Procedure time, mean ± SD (range) (min)	198 ± 43 (120−285)
Number of catheters per patient	1.05

PV = pulmonary vein; SD = standard deviation.

pressure to ensure adequate balloon/tissue contact. By using the adjustable 30° aiming arc for guidance, laser energy (5.5−16 W, 20−30 seconds) was delivered around the PV ostium in a contiguous manner with 30%−50% lesion overlap. The lowest dose of 5.5 W/30 seconds was used in areas that were adjacent to or were overlapping with blood. After initial encirclement, PV electrograms were again assessed and additional laser energy was delivered to sites of electrical breakthrough if PV isolation was not present. The site of electrical breakthrough was identified by recording the earliest PV electrogram on the circular mapping catheter and correlating that to the anatomic position in the PV by using fluoroscopy. This was recorded as clock position for each PV (eg, 3 o'clock in left superior PV corresponds to the anterior portion of the PV near the left atrial ridge). Subsequently, laser energy was delivered to the anatomic site of electrical breakthrough to achieve isolation. For left-sided PVs, pacing from the left atrial appendage was performed if PV electrograms could not be distinguished from far-field appendage potentials. When present, isolated PV potentials identified exit block. However, pacing from within the PV was not routinely performed. After PV isolation was achieved, it was again reassessed at 30 minutes postablation. During ablation of the right-sided PVs, phrenic nerve pacing was performed to monitor for phrenic nerve injury. An esophageal temperature probe was used in all cases to monitor for esophageal heating. Ablation was stopped when esophageal temperature reached ≥38.5°C.

At ~3 months, all patients returned for a second procedure, regardless of symptomatology. The second procedure was performed in a manner similar to that of the first procedure. After 1 or 2 transseptal punctures, the PVs were assessed for electrical isolation by using a circular mapping catheter in a manner similar to that of the first procedure. If PV isolation was not present, then ablation was performed at sites of electrical breakthrough by using an externally irrigated radiofrequency ablation catheter (Celsius or Navistar ThermoCool, Biosense-Webster, Inc, Diamond Bar, CA). Postprocedure, anticoagulation and antiarrhythmic drugs were used at the discretion of the physicians.

Statistics

Normally distributed continuous data are presented as mean and standard deviation. Comparisons between groups were made by using the Student *t* test. Continuous data with skewed distribution are represented as median with interquartile ranges. Categorical variables were compared by using the Fisher exact test. A 2-sided alpha level of .05 was used for all superiority testing.

Results

Patient demographics

The mean age of the 56 patient cohort was 57.1 ± 9.7 years (range 31−75 years), and 40 (71%) of the patients were men. The median duration of paroxysmal AF was 4.0 years (2.0–7.0; Q1−Q3). Coronary artery disease was present in 6 (11%) patients and hypertension in 27 (40%) patients.

Initial ablation procedure characteristics

In the 56 patients, a total of 206 PVs were targeted (Table 1). Acute PV isolation was achieved in 202 of 206 PVs (98.1%) and was independent of PV type (Table 2). Complete electrical isolation of all PVs was achieved in 53 of 56 (94.6%) patients (Figure 1). It took an average of 1.3 attempts per PV (wherein the initial attempt is defined as the placement of a fully circumferential series of overlapping laser lesions). After the placement of the initial encircling lesion set, 83% of PVs were isolated. A total of 38.3 lesions per PV were delivered to achieve electrical isolation. On a per-patient basis, the mean laser and ablation times were 64 ± 15 and 113 ± 38 minutes, respectively. On a per-PV basis, it took an average of 17.1 minutes per PV of laser time and 30.3 minutes per PV of total ablation time to achieve PV isolation. The mean fluoroscopy and procedure times were 23 ± 15 and 198 ± 43 minutes, respectively. The number of balloon catheters required per patient was 1.05. Two catheters were required in 4 patients because of malfunction rather than balloon/PV size mismatch. A representative example of an endoscopic view during ablation around the left superior PV is shown in Movie 1.

Table 2 Acute and chronic PV isolation rates based on PV type

	n (%)	
	Acute PV isolation (N = 206)	Chronic PV isolation (N = 189)
Left superior	44 of 45 (97.8)	35 of 41 (85.4)
Left inferior	43 of 44 (97.8)	37 of 41 (90.2)
Left common	10 of 11 (91.0)	9 of 10 (90.0)
Right superior	53 of 53 (100)	39 of 49 (79.6)
Right inferior	50 of 51 (98.0)	40 of 46 (87.0)
Right common	2 of 2 (100)	2 of 2 (100)

PV = pulmonary vein.

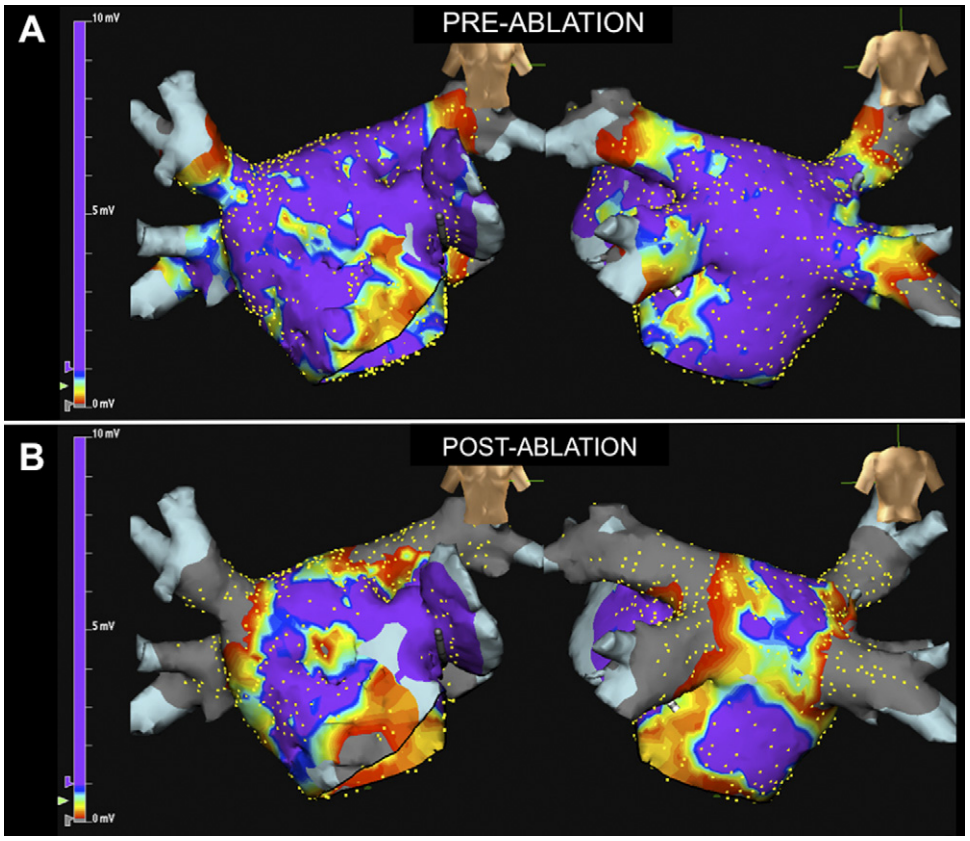

Figure 1 Voltage maps pre- and postablation. Baseline **(A)** and postablation **(B)** bipolar voltage maps are shown for a patient who underwent PV isolation utilizing the VGLA catheter in anteroposterior (left) and posteroanterior (right) projections. The voltage maps were superimposed on 3-dimensional CT angiograms of the left atrium. The color range of the voltage map spans from 0.1 mV (gray) to 1.0 mV (purple) and shows electrical isolation at the level of the PV ostia. The antrum is largely unablated. CT = computed tomography; PV = pulmonary vein; VGLA = visually guided laser ablation.

Four targeted PVs (1 left common, 1 right inferior, 1 left superior, and 1 left inferior) in 3 patients were not isolated at the initial procedure. One patient developed a pericardial effusion and cardiac tamponade during ablation of the left common PV. The effusion was drained, and the remainder of the procedure was abandoned. Thus, during this procedure, only 1 PV was targeted with the VGLA catheter and was not isolated. In a second patient, the left superior and inferior PVs were not isolated despite multiple attempts. The right superior and inferior PVs were successfully isolated in this patient. In the third patient, only the right inferior PV could not be isolated following multiple attempts. None of these PVs were targeted with radiofrequency ablation.

PV remapping

Of the 56 patients, 52 returned for PV remapping at a mean of 105 ± 44 days (range 60−245 days). In these patients, 189 of 193 (97.9%) targeted PVs were successfully isolated at the initial procedure. At the time of PV remapping, 162 (85.7%) of these 189 PVs remained electrically isolated. Although acute PV isolation rates were >90% for all PV types, durable isolation rates varied from 80% to 90% for all PVs, except for the 2 right common PVs for which the durable PV isolation rate was 100% (Table 2). Data pertaining to the number of attempts necessary to isolate each PV at the time of the first procedure were available for 186 of these 189 PVs. Of the 160 PVs that were isolated after the placement of the initial encircling lesion set at the first procedure, 142 (88.8%) PVs remained persistently isolated at remapping. Of the 26 PVs that required more than 1 attempt to achieve electrical isolation, 20 (76.9%) PVs remained persistently isolated at remapping (P = .114). However, persistently isolated PVs needed a mean of 1.2 ± 0.7 attempts per PV to achieve acute isolation during the first procedure compared with 1.5 ± 1.1 attempts per PV for those that reconnected (P = .044).

At the time of PV remapping, 32 (61.5%) patients had all the PVs persistently isolated. In the 20 (38.5%) patients with PV reconnections, 1 patient was the acute procedural failure as the initial procedure was terminated because of pericardial effusion during the isolation of the left common PV. In the remaining 19 patients, there were a total of 27 PVs that were electrically reconnected at remapping after initial successful isolation. When comparing patients with PV reconnections vs those with all PVs persistently isolated (Table 3), there were no differences in the number of ablation lesions or the duration of laser energy delivered during the first procedure. However, patients with PV reconnections had a significantly higher percentage of 5.5 W/30

Table 3 Initial ablation procedure data for patients with and without chronic PV reconnections

	PV reconnections	No PV reconnections	*P*
Patients, n	19	32	–
PVs isolated, n (%)	45 of 72 (62.5)	120 of 120 (100)	–
Ablation lesions per patient, mean ± SD	146 ± 32	142 ± 28	.618
Laser time, mean ± SD (min)	68 ± 16	62 ± 15	.183
5.5 W/30 s laser time (%)	71 ± 14	53 ± 17	<.001

SD = standard deviation.

seconds energy delivery time (71% ± 14% vs 53% ± 17%; $P < .001$).

A single PV was reconnected in 14 (73.7%) patients, 2 PVs in 4 (21.1%) patients, and all PVs in 1 (5.3%) patient. All reconnected PVs had a single focal area of reconnection with the exception of 1 PV that had 2 distinct areas of electrical reconnection. The sites of reconnection are illustrated in Figure 2. Sites of PV reconnections for the left-sided PVs were concentrated in the anterior aspect adjacent to the left atrial appendage and the anterior carina between the superior and inferior veins. These locations accounted for 10 of 11 (90.9%) reconnection sites for the left-sided veins. There was only 1 (9.1%) PV reconnection located at another site—the posterior wall. The pattern of PV reconnections for the right-sided PVs was less distinct.

For operators who had performed ≥10 procedures (n = 2), the rate of persistent PV isolation at the time of remapping was 89.4% (127 of 142 PVs) compared with 73.1% (38 of 52 PVs) for those who had performed <10 procedures (n = 7) ($P = .011$) (Figure 3). Similarly, the percentage of patients with all PVs persistently isolated at the time of remapping was 65.8% (25 of 38 patients) for operators performing ≥10 procedures compared with 57.1% (8 of 14 patients) for those performing <10 procedures ($P = .746$).

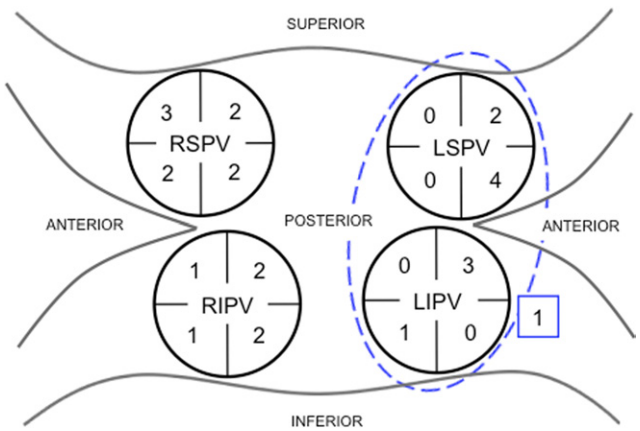

Figure 2 Sites of chronic PV reconnections. For PVs that were successfully isolated at the initial procedure, the focal areas of electrical reconnection are shown in this anterior posterior illustration of the left atrium and PVs. The total number of reconnections per quadrant in each PV is shown. There was a single PV reconnection in the anterior inferior quadrant involving the left common PV (dashed, blue line). There was 1 PV reconnection involving the right superior PV, which is not shown because of the lack of information on the reconnection site. PV = pulmonary vein. LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein.

Clinical follow-up

In the 52 patients who underwent PV remapping procedures, at 12.0 ± 1.8 (range 7−15) months of follow-up, the drug-free rate of freedom from AF or atrial tachycardia was 71.2%. Of the 32 patients who had all PVs persistently isolated at remapping and no ablation was performed during the second procedure, 23 patients (71.9%) remained free of AF without antiarrhythmic medications. In the 20 patients in whom the reconnected PVs were reisolated, 14 patients (70.0%) remained free of AF without antiarrhythmic medications.

Safety

There were no atrial esophageal fistulas, transient ischemic attacks/strokes, or deaths. There was 1 patient with cardiac tamponade that was successfully drained percutaneously. A large groin hematoma requiring transfusion occurred in 1 patient. Phrenic nerve injury occurred in 1 patient. This resolved by the time of the 3-month PV remapping procedure. There were no instances of significant PV stenosis (>50% decrease in diameter). There were no procedure-related complications related to the remapping procedures.

Discussion

The goal of catheter-based therapy for paroxysmal AF is durable PV isolation. While acute PV isolation is achieved in virtually all cases, chronic efficacy is often limited by the resumption of conduction between the PVs and the left atrium.[5–12] In this multicenter experience, we have shown that a high rate of acute and durable PV isolation can be achieved by using the VGLA catheter. Acute PV isolation was achieved in 98% of targeted PVs. At ~3 months, 86% of PVs were persistently isolated and 62% of patients had all PVs still isolated. Similar to the experience with any new technology, there was a statistically significant improvement in outcome with operator experience: from 73% to 89% of PVs being durably isolated ($P = .011$). After 2 procedures and 12 months of follow-up, the drug-free rate of freedom from AF or atrial tachycardia was 71%.

Disparity between durable PV isolation rates and clinical efficacy

When considering the 86% rate of durable PV isolation at ~3 months and the reisolation of reconnected PVs during

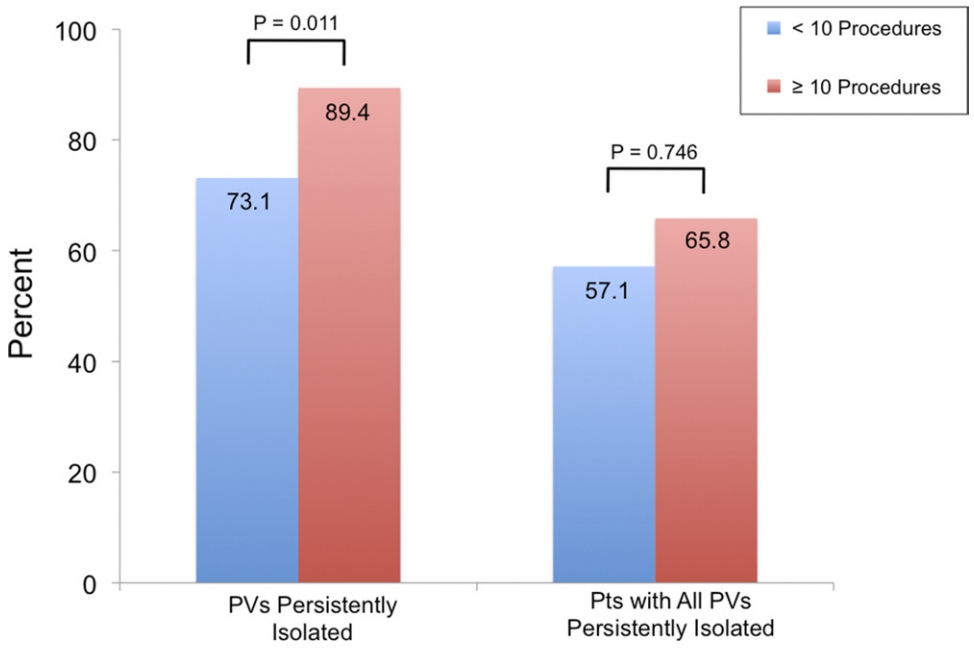

Figure 3 Operator experience vs PV reconnection rate. The percentage of PVs that were persistently isolated and the percentage of patients with all PVs persistently isolated at the time of remapping are shown for operators who performed <10 and ≥10 procedures. Pts = patients; PV = pulmonary vein.

remapping, the expected clinical efficacy would be greater than that observed in this study. One potential explanation for this disparity may be that the level of electrical isolation achieved with the VGLA catheter is close to the PV ostium and excludes areas within the antrum that may be responsible for the initiation and perpetuation of AF.[18] With the prior-generation VGLA catheter and other balloon ablation catheters, electrical isolation has been shown to occur at the level of the PV ostia with antral regions being largely unaffected.[19] Data pertaining to the level of electrical isolation with the current-generation VGLA catheter are limited to several cases in which electroanatomical mapping was performed immediately postablation or at the time of PV remapping (Figure 1). Based on our limited experience, the level of electrical isolation achieved with the current-generation VGLA catheter is likely not as antral as desired. A second explanation may be the presence of other non-PV triggers of AF that may be responsible for the initiation of AF in ~20% of patients.[20–24] It is possible that a combination of the above 2 factors is responsible for the observed disparity between the high rate of durable PV isolation and clinical efficacy.

Improving durable PV isolation rates with the VGLA catheter

In patients with PV reconnections, there was a higher percentage of low energy (5.5 W/30 seconds) delivery time. One potential explanation for this is that transmural lesions are not always achieved at this dose. This may be particularly relevant in areas in which the tissue is thicker, such as the left atrial appendage ridge, which accounted for 38% of overall PV reconnections and 91% of reconnections involving the left-sided PVs.

PVs that were reconnected at remapping required more attempts to achieve acute isolation during the first procedure than did those that were persistently isolated (1.5 ± 1.1 vs 1.2 ± 0.7 attempts per PV; $P = .044$). This difference may be due, in part, to edema from prior lesions limiting the quality of subsequent lesions. In addition, lesion visualization and energy delivery is not straightforward. Ablation lesions are often difficult to visualize and delivery of energy with 30%−50% lesion overlap, while conceptually straightforward, may not occur unless one is vigilant to carefully monitor and stabilize the location of the aiming/ablative arc to the same location during energy delivery.

Therefore, complete encirclement of each PV with good lesion overlap and maximization of laser energy dose, particularly in areas of thick tissue such as the left atrial appendage ridge, may further improve durable PV isolation rates with the VGLA catheter.

Study limitations

With the VGLA catheter, simultaneous assessment of PV isolation during ablation is not possible and represents a limitation of the technology. Although the VGLA catheter was designed to have an adjustable diameter to accommodate all PVs, mean balloon diameters during deployment in the various PVs were not recorded. During the blanking period, monitoring for arrhythmia recurrence was not performed and therefore we are unable to correlate this with the presence or absence of durable PV isolation during the remapping procedures. In addition, for the remapping procedures, procedural data were not recorded. The results of this multicenter experience with the VGLA catheter are encouraging with respect to the high rates of durable PV isolation. Despite this, the clinical efficacy appears similar

to that of radiofrequency ablation. Large multicenter, randomized, comparative studies are necessary to fully delineate the true efficacy of each treatment modality.

Conclusions

A high rate of acute PV isolation can be achieved with the compliant, variable-diameter, visually guided laser balloon alone, without the need for adjunctive spot ablation catheters. This high rate of acute PV isolation is durable, with 86% of PVs remaining isolated at 3 months. However, the clinical efficacy appears similar to that of radiofrequency ablation. Multicenter, randomized trials are needed to properly compare the efficacy of both treatment modalities.

Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://doi:10.1016/j.hrthm.2012.01.019.

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