Pulmonary Vein Isolation Using a Visually-Guided Laser Balloon Catheter: The First 200-Patient Multicenter Clinical Experience

Running title: Dukkipati et al.; Visually-Guided AF Ablation

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Abstract

**Background** - Because of the technical difficulty with achieving pulmonary vein (PV) isolation in the treatment of patients with paroxysmal atrial fibrillation (PAF), novel catheter designs to facilitate the procedure are in development. A visually-guided laser ablation (VGLA) catheter was designed to allow the operator to directly visualize target tissue for ablation, and then deliver laser energy to perform point-to-point circumferential ablation. Single center studies have demonstrated favorable safety and efficacy. We sought to determine the multicenter feasibility, efficacy, and safety of performing PV isolation using the VGLA catheter.

**Methods and Results** - This study includes the first 200 PAF patients treated with the VGLA catheter (33 operators, 15 centers). After transseptal puncture, the VGLA catheter was used to perform PV isolation. Electrical isolation was assessed using a circular mapping catheter. Using the VGLA catheter, 98.8% (95% CI, 97.8-99.5%) of targeted PVs were isolated using a mean of 1.07 catheters/patient. Fluoroscopy and procedure times were 31±21 (mean±sd) and 200±54 min respectively, and improved with operator experience. There were no instances of stroke, TIA, atrio-esophageal fistulas or significant PV stenosis. There was a 2% incidence of cardiac tamponade and 2.5% incidence of phrenic nerve palsy. At 12 months, the drug-free rate of freedom from atrial arrhythmias after one or two procedure was 60.2% (95% CI, 52.7-67.4%)

**Conclusions** - In this multicenter experience of the first 200 patients treated with the VGLA catheter, PV isolation can be achieved in virtually all patients using a single VGLA catheter with an efficacy similar to radiofrequency ablation.

**Key words:** atrial fibrillation, catheter ablation, pulmonary vein isolation, lasers, visual guidance
Introduction

Pulmonary vein (PV) isolation is the mainstay of catheter ablative therapy for patients with paroxysmal atrial fibrillation (AF). While conceptually straightforward to consider placing a series of point-by-point ablation lesions to circumferentially isolate the PVs, in practice, these procedures are technically challenging to perform. Accordingly, there has been a tremendous amount of development work in designing various one-size-fits-all ablation catheters to facilitate PV isolation. For such devices to be practical, they need to be able to isolate PVs: (i) reproducibly using only a single catheter despite the intra- and inter-patient variability in PV size, shape and orientation, (ii) without requiring the use of ancillary catheters for ‘touch-up’ energy delivery, (iii) without a high rate of complications, (iv) with reasonable procedure times and without excessive fluoroscopy exposure, and (v) with good clinical efficacy.

To this end, a novel balloon-based visually-guided laser ablation (VGLA) catheter has recently been shown in single-center experiences to be able to safely and effectively isolate pulmonary veins. This balloon catheter permits: (i) real-time endoscopic visualization of the target tissue via a 2-Fr endoscope, (ii) a maneuverable 30-degree light arc to deliver laser energy (980 nm) to ablate the target tissue, and (iii) a variable-sized, deformable balloon material to accommodate variable-sized/shaped PVs. This novel ablation catheter was approved in Europe for general clinical use, and is in the midst of FDA investigational trials in the United States. In this manuscript, we report on the international multicenter experience of the first 200 paroxysmal AF patients treated with this visually-guided laser ablation catheter.

Methods

The study consists of 200 patients (out of a consecutive series of 204 patients) enrolled in 1 US study (9 clinical sites) and 3 European studies (6 clinical sites). Of note, 4 additional patients
who underwent ablation near the end of the 200 patient series were excluded as baseline
demographics and procedural data were not available at the time of data analysis; however, none
of these excluded patients experienced any procedural complications. All of the studies were
approved by institutional review committees at the participating institutions, and all subjects
gave informed consent. The authors had full access to and take full responsibility for the
integrity of the data. All authors have read and agree with the manuscript as written.

**Patient Selection & Study Design:** All 4 clinical studies were open label, non-randomized
studies of patients with symptomatic, recurrent, paroxysmal AF. There were only minimal
differences in the inclusion criteria between the studies. Key inclusion criteria were: age 18-75
years, and recurrent paroxysmal atrial fibrillation that was refractory to at least one anti-
arrhythmic drug (Class I – IV). All patients were otherwise deemed to be candidates for catheter
ablation. Key exclusion criteria included: a left ventricular ejection fraction <30%, LA diameter
>5 cm, PV diameters >32 mm (for oval PVs, the mean of the major and minor dimensions were
used), the presence of an intracardiac thrombus, prior cardiac ablation, myocardial infarction or
cardiac surgery within the prior 3 months, moderate or severe valvular heart disease, or a
stroke/transient ischemic attack within prior 6 months. Pre-procedural CT or MRI scans were
performed to assess LA and PV anatomy and size.

Following the procedure, patients were discharged on oral anticoagulation (warfarin), and
at times, low molecular weight heparin until the international normalized ratio was ≥2.0.
Following the procedure, anti-arrhythmic medications were typically continued for 1 to 3 months
after which they were completely discontinued. There was a 3 month blanking period following
ablation. Follow-up methods were variable between the four studies and included clinic visits at
3 or 6 month intervals, and either Holter or transtelephonic monitoring at variable intervals.
Recurrence was defined as any atrial arrhythmia, whether symptomatic or not of a duration exceeding 60 sec. In a subset of patients, a repeat CT or MRI scan was performed at 3 months to assess for PV stenosis.

One study required that all patients return at three months for PV remapping procedures, regardless of symptomatology. These patients underwent re-isolation of reconnected PVs with radiofrequency energy. The results of the PV remapping and one year clinical follow-up in 52 of these patients have been previously reported.11 A single center experience in an additional 40 of these patients, with one year follow-up was also previously reported.12

**The Balloon-Based Visually-Guided Laser Ablation (VGLA) Catheter:** The components of VGLA catheter (CardioFocus, Inc., Marlborough, Massachusetts) were previously described in detail.9 The VGLA catheter is a variable-diameter, compliant balloon that is delivered through a deflectable 12-Fr sheath. Within the central shaft of the balloon is a 2-Fr endoscope that provides real-time visualization of the face of the balloon: both the tissue and blood in contact with the balloon. Additionally, within the central shaft are additional lumens for circulating D2O to cool the balloon, and a maneuverable optical fiber that generates a 30° arc/spot of both visible and near-infrared ablative light energy. The tip of the VGLA catheter is designed to be flexible to cause minimal trauma.

The deflectable sheath was positioned at the PV ostium and the VGLA catheter advanced and inflated to provide good tissue contact. Under endoscopic visualization, the area of tissue-balloon contact appears white and blood appears red. The endoscopic field of view is partially obscured in the region behind the central shaft. This partially obscured region is located 180° directly opposite a radiopaque marker located on the catheter shaft. The location/orientation of the radiopaque marker on fluoroscopy is then correlated to the endoscopic image thus defining
superior, inferior, anterior, and posterior directions. The 30° arc of light includes a visible aiming beam and can be advanced/retracted and rotated to any location on the face of the balloon. Once an appropriate site for ablation is identified, diode laser energy (980 nm) is delivered through the same optical fiber that generates the aiming beam to ablate tissue. Ablation lesions are placed in a contiguous and overlapping manner to achieve electrical isolation of the PV.

**Pulmonary Vein Isolation Procedure:** Procedures were performed using either conscious sedation or under general anesthesia per the institution’s clinical practice. Right and left femoral vein access was obtained. The transseptal puncture was performed in standard fashion with an 8-Fr sheath and a Brockenbrough needle under fluoroscopic guidance, and at some centers with adjunctive intracardiac echo guidance. The 8-Fr sheath was then exchanged for a 12-Fr deflectable sheath over a 0.035” or 0.038” guidewire. Per the operator preference, a second transseptal puncture with a standard 8-Fr sheath was placed for a diagnostic mapping catheter. At baseline, a multi-electrode circular mapping catheter was used to assess electrograms of all PVs. Throughout the procedure, intravenous heparin was administered as boluses and a continuous infusion to maintain an activated clotting time >300 sec.

The deflectable sheath was positioned at the ostium of the target PV and the VGLA catheter was advanced and inflated. Ablation lesions were placed circumferentially around the PV in a contiguous and overlapping manner. Although initially not available, the more recent procedures were performed with custom software that was used to track prior ablation lesions to minimize gaps. The balloon was then partially deflated, rotated, and re-inflated to allow ablation in the region behind the partially obscured area. After placing the encircling lesion set, the multi-electrode circular mapping catheter was again used to assess for PV isolation. If the PV
was not isolated, the VGLA catheter was again used to deliver lesions to the area of anatomical breakthrough. All PVs were targeted in a similar manner. During ablation of the right sided PVs, phrenic nerve pacing was performed from the superior vena cava to monitor for impending injury. In all patients, an esophageal temperature probe was placed in the esophagus to monitor for excessive heating. Ablation was stopped, if esophageal temperature exceeded 38.5°C. After 30 minutes post-ablation of the last PV, all PVs were reassessed for electrical isolation. A circular mapping catheter was used to identify entrance block. Exit block was not routinely assessed. For situations when entrance block was ambiguous, pacing from the superior vena cava (for right superior PVs) and left atrial appendage (for left PVs) was used to distinguish between far-field vs. near-field potentials. Isoproterenol and Adenosine administration were not mandated in any of the protocols.

The dose of laser energy used was 5.5 Watts x 30 seconds or 8–14 Watts x 20 seconds per lesion. When the area of balloon/tissue contact was not adequate enough to allow energy delivery to atrial tissue alone, the lowest energy dose (5.5 Watts/30 sec) was used to simultaneously ablate on tissue and blood that was located at the periphery of the target tissue. Blood located at the periphery of the target tissue is continually refreshed (not trapped by the balloon), and ablation at these sites with the lowest energy dose minimizes the risk of thrombus formation.

Statistics. Categorical variables were compared using Fisher’s exact test. Continuous variables were first tested for normality using the Shapiro–Wilk test for normality to determine if the data were normally distributed. All tested continuous variables were determined to have a normal distribution. Comparisons between groups were tested using Student’s two-sample t-test (pooled). Continuous data are presented as mean and standard deviation (mean±SD).
Continuous data with skewed distribution are represented as median with interquartile ranges. Point estimates (i.e. percentage of PVs isolated and percentage of patients free of AF at 12 months) are represented with 95% confidence intervals (95% CI). A two-sided alpha level of 0.05 was used for all superiority testing. Statistical analyses were conducted using SAS version 9.2.

**Results**

**Patient Demographics:** The baseline demographics of the 200 patients are shown in Table 1. The mean age of the cohort was 57.0 ± 9.9 years (limits 25–75) and 60% were male. The median duration of symptoms consistent with paroxysmal AF was 3.0 years (1.0–7.0, Q1–Q3). A total of 187 (93.5%) patients failed at least one antiarrhythmic medication. Transthoracic echocardiograms were performed in 178 patients and demonstrated a mean LA diameter of 4.1±0.5 cm and mean left ventricular ejection fraction (LVEF) of 63±8%. No patients were excluded due inappropriate PV anatomy (i.e., a PV with average diameter >32 mm). These 200 patients were treated by a total of 33 primary operators at 15 centers.

**Procedural Characteristics:** A total of 770 PVs were targeted in 200 patients (Tables 2 & 3). Acute electrical isolation was achieved in 78.4% (95% CI, 75.4-81.3%) of all PVs after placement of the initial encircling lesion set and ultimately in 98.8% (95% CI, 97.8-99.5%) of PVs after an average of 1.3 attempts per vein. Of the various PVs, the left common PVs and left superior PVs were the least likely to be isolated after the first encircling lesion set (Table 3): that is, although 100% of left common PVs and 98.3% of left superior PVs were ultimately isolated, only 58.6% and 69.9% were isolated after the first encircling lesion set, respectively. Overall, the PVs were isolated using an average of only 1.07 catheters per patient. Two catheters were
required in 13 (6.5%) patients; all due to catheter damage during use rather than PV/balloon size mismatch. No additional catheters were used to provide ‘touch-up’ energy delivery.

The mean procedure and fluoroscopy times were 200±54 min and 31±21 min, respectively. As shown in Figure 1, these parameters improved with operator experience. With increased operator experience (first 15 cases performed by an operator vs. cases beyond the first 15), procedure times decreased by 30±55 min (p=0.0005), ablation times decreased by 18±36 min (p=0.001), and fluoroscopy times decreased by 18±19 min (p<0.0001). Four of the 33 operators performed more than 15 procedures. Interestingly, the ability to electrically isolate a PV after placement of the initial encircling lesion set did not significantly change with operator experience. That is, for operators performing ≤15 procedures, 77% of PVs were isolated after the first encircling lesions set, and for those performing >15 procedures, 82% were isolated (p=0.462).

**Clinical Outcomes & Safety**: Of the 200 patients, 181 completed 12 months of follow-up. Of these, 60.2% (95% CI, 52.7-67.4%) of patients were free from AF and were off anti-arrhythmic drugs (class I or III). After a single procedure 72/123 (58.5%) patients were free of atrial arrhythmias off anti-arrhythmic drugs (95% CI, 49.3-67.4%), and after two procedures 37/58 (63.8%) were free of atrial arrhythmias off anti-arrhythmic drugs (95% CI, 50.1-76.0%). Of the 19 patients with no outcome data, 7 were lost to follow-up, 6 withdrew from study, and 6 had not yet achieved 12 months of follow-up.

There was no clinical evidence of PV stenosis in any of the patients. In addition, baseline and 3 month CT or MRI scans were available for 116 patients (Table 4). At 3 months, the mean decrease in PV diameter was 3.5%. Mild PV narrowing (1 to 25% decrease in diameter) was present in 44% of PVs, and moderate PV narrowing (26 to 50% decrease) in 6% of PVs. There
was no significant PV stenosis (>50% decrease). A variable degree of mild to moderate PV
diameter increase was also noted.

Phrenic nerve injury related to the VGLA occurred in 5 patients, 1 of which remain
unresolved at 12 months of follow-up (Table 5). Pericardial effusions were reported in 6
patients, 4 of whom developed hemodynamic compromise / cardiac tamponade. All of these
tamponades occurred during the procedure and were successfully drained. One patient with
cardiac tamponade underwent pericardiocentesis and was ultimately discharged in good
condition on the fourth hospital day. Two days after discharge from the hospital, he experienced
sudden death. Autopsy demonstrated no pericardial effusion, cardiac perforation, atrio-
esophageal fistula, or pulmonary embolization. However, the patient was found to have
unrecognized, critical triple vessel coronary artery disease (a pre-procedure stress test had
revealed only a mild reversible apical defect and was thought not to be clinically significant).
Accordingly, while the stress of the AF ablation procedure may have contributed to this death, an
independent Data Safety and Monitoring Board adjudicated that this event was not related
specifically to the laser ablation catheter. The presumed cause of death was felt to be
arrhythmic. There were no patients who manifested transient ischemic attacks, strokes, or atrio-
esophageal fistulas.

Discussion

In this manuscript we report the international multicenter experience of the first 200 patients
treated with this novel VGLA catheter. In procedures performed by 33 operators at 15 centers,
the compliant, variable diameter VGLA catheter was capable of achieving PV isolation in 99%
of targeted veins utilizing (in the majority of cases) only 1 balloon catheter, irrespective of PV
size and anatomy. With visual guidance alone, 78% of PVs were isolated after placing the first
encircling lesion set. The mean procedure time was relatively long (200±54 min), but did improve with operator experience, as one would expect with new technology. At 12 months, the drug-free rate of freedom from atrial arrhythmias was 60%. These results were obtained without any instances of significant PV stenosis, stroke/TIA, or atrio-esophageal fistula. However, there was a 2% incidence of pericardial tamponade and a 3% incidence of phrenic nerve injury.

**Efficacy of the VGLA catheter:** While acute PV isolation was achieved in virtually all targeted PVs, the observed clinical efficacy was similar to that seen with radiofrequency energy and cryoballoon ablation. As with other technologies, it would seem to reason that clinical efficacy is limited by chronic PV reconnections. However, in a subset of these patients, we previously showed that a high rate of acute PV isolation translated to 62% of patients having persistent PV isolation of all veins at 3 months.11 In that study, reconnected PVs were re-isolated with radiofrequency energy, but still resulted in AF recurrence in 29% of patients at one year. Therefore, PV reconnections alone are unlikely to account for the 40% recurrence at one year in this study. Other possibilities include the presence of non-PV triggers, and an ostial level of electrical isolation that largely excludes areas in the antrum that may be responsible for the initiation and perpetuation of AF.16,17 We previously have shown that the level of electrical isolation with the first generation VGLA catheter is at the PV ostium.2 The level of isolation with the current generation VGLA catheter has not been systematically evaluated. However, limited data from cases where electroanatomical mapping was performed with VGLA, suggests that the level of electrical isolation maybe near the PV ostia.11 Further improvement in chronic PV isolation rates and clinical efficacy with VGLA may depend upon the use of high-energy ablation, particularly in areas of increased tissue thickness such as the left atrial appendage ridge, where PV reconnections commonly occur with VGLA.11,14


**Safety of the VGLA:** There were two important safety issues that were observed in this 200-patient experience, albeit at a low event rate. The first of these was a 2% rate of pericardial tamponade. This is possibly due, in part, to the inability to use an over-the-wire technique when positioning the VGLA catheter. This is still a manageable rate given the uncensored nature of the data. That is, it is likely that this tamponade rate will decrease after operators have passed their learning curve. While the VGLA catheter was designed with an atraumatic tip, it has recently been modified to further decrease its stiffness and render it even less traumatic. Only future data will reveal whether this has the intended effect of decreasing the incidence of cardiac tamponade.

The second safety event noted in this 200-patient experience was phrenic nerve injury – observed in 2.5% of the patients. The majority of these have resolved at one year with only 1/5 patients still having persistent injury. Phrenic nerve injury has been described with other balloon catheters, including the cryoballoon. However, unlike with the cryoballoon catheter, the anatomic location of lesion delivery can be tailored according to anatomy. Therefore, delivery of a more antral lesion set around the right sided PVs in locations that are susceptible to phrenic nerve injury may help decrease this complication.

While some degree of PV narrowing was observed, there was no significant stenosis associated with the VGLA catheter in this study. Although repeat CT scans were not performed on all patients, there were no cases of clinical PV stenosis in any of the patients during one year of follow-up.

**Limitations:** This study is a composite of several open-label, non-randomized, clinical studies and was not a single study with a uniform protocol. Pre- and post-procedural CT scans were not routinely performed, and when done, were not assessed by a core lab. Therefore, caution should
be exercised in interpreting degree of PV stenosis. However, there were no cases of clinically significant PV stenosis seen in the study. A major limitation is the non-uniformity in follow-up and AF monitoring methods that may have lead to an overestimate of the true clinical efficacy. Multicenter, randomized trials with long-term follow-up are needed to truly assess the clinical efficacy. There was a 6.5% catheter failure rate; that is, a second ablation catheter was required in 13 cases. But it should also be noted that this is the initial use of this novel technology and one could reasonably expect that this failure rate will improve over time. And most importantly, the reason for additional catheters was not due to PV/balloon size mismatch; that is, additional catheters were not required to provide ‘touch-up’ energy delivery.

Conclusions

In this multicenter evaluation of the first 200 patients treated with the compliant, variable diameter, visually-guided laser balloon catheter, acute PV isolation was achieved in 99% of targeted veins with a single balloon catheter. The catheter also proved to be reasonably safe, with no instances of embolic stroke / TIA, PV stenosis, or atrio-esophageal fistula. On the other hand, there remains a low rate of pericardial tamponade and phrenic nerve injury. The clinical efficacy was similar to other AF ablation technologies. This favorable experience sets the stage for truly comparative long-term efficacy and safety studies (versus radiofrequency ablation).

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Conflict of Interest Disclosures: KHK, PN, IW, JK, HTM, EPG, SKD, RH, and VYR received
research grant support from CardioFocus, Inc. KHK serves as consultant for CardioFocus, Inc. JNR served on the clinical oversight committee for one of the studies (no compensation). SRD, KHK, BS, and AM received honoraria from CardioFocus, Inc. The remaining authors report no conflicts.

References:


Table 1. Patient Demographics.

<table>
<thead>
<tr>
<th></th>
<th>N = 200</th>
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</thead>
<tbody>
<tr>
<td>Age, mean±SD (limits)</td>
<td>57.0±9.9 (25–75)</td>
</tr>
<tr>
<td>Gender, M/F (%)</td>
<td>120 (60%) / 79 (40%)</td>
</tr>
<tr>
<td>Duration of AF, median years (Q1-Q3)</td>
<td>3.0 (1.0 – 7.0)</td>
</tr>
<tr>
<td>Coronary Artery Disease, n (%)</td>
<td>20 (10.0%)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>112 (56.0%)</td>
</tr>
<tr>
<td>Ejection Fraction, mean±SD (limits) *</td>
<td>63±8% (30–88%)</td>
</tr>
<tr>
<td>LA Diameter, mean±SD (limits)*</td>
<td>4.1±0.5 cm (2.7–5.6)</td>
</tr>
</tbody>
</table>

Anti-Arrhythmic Medications†

<table>
<thead>
<tr>
<th>Class</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>122 (39.5%)</td>
</tr>
<tr>
<td>II</td>
<td>85 (27.5%)</td>
</tr>
<tr>
<td>III</td>
<td>98 (31.7%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (1.9%)</td>
</tr>
</tbody>
</table>

* Available from 178 patients.
† 187 patients failed a total of 309 anti-arrhythmic medications.

Table 2. Ablation Data

<table>
<thead>
<tr>
<th></th>
<th>N = 200</th>
</tr>
</thead>
<tbody>
<tr>
<td># PV Isolated (%)</td>
<td>761/770 (98.8%)</td>
</tr>
<tr>
<td># PVs isolated on First Attempt (%)</td>
<td>604 (78.4%)</td>
</tr>
<tr>
<td># Attempts to isolate/PV, mean</td>
<td>1.3</td>
</tr>
<tr>
<td># Ablation Lesions per Patient</td>
<td>147±35</td>
</tr>
<tr>
<td># Catheters per Patient</td>
<td>1.07</td>
</tr>
<tr>
<td>Fluoroscopy Time, min (limits)</td>
<td>31±21 (3–135)</td>
</tr>
<tr>
<td>Laser Ablation Time, min (limits)</td>
<td>108±36 (34–236)</td>
</tr>
<tr>
<td>Procedure Time, min (limits)</td>
<td>200±54 (85–358)</td>
</tr>
</tbody>
</table>
Table 3. Number and Type of Pulmonary Veins Isolated

<table>
<thead>
<tr>
<th></th>
<th>N = 770</th>
<th>PVs Isolated</th>
<th>PVs Isolated on First Attempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Superior</td>
<td>173</td>
<td>170 (98.3%)</td>
<td>121 (69.9%)</td>
</tr>
<tr>
<td>Left Inferior</td>
<td>171</td>
<td>170 (99.4%)</td>
<td>137 (80.1%)</td>
</tr>
<tr>
<td>Left Common</td>
<td>29</td>
<td>29 (100%)</td>
<td>17 (58.6%)</td>
</tr>
<tr>
<td>Right Superior</td>
<td>195</td>
<td>194 (99.5%)</td>
<td>160 (82.1%)</td>
</tr>
<tr>
<td>Right Inferior</td>
<td>194</td>
<td>191 (98.5%)</td>
<td>162 (83.5%)</td>
</tr>
<tr>
<td>Right Common</td>
<td>5</td>
<td>4 (80.0%)</td>
<td>4 (80.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>3 (100%)</td>
<td>3 (100%)</td>
</tr>
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</table>

Table 4. Pulmonary Vein Diameter Change on 3 Months Post-Ablation CT Scans.

<table>
<thead>
<tr>
<th>Pulmonary Veins</th>
<th>N (%)</th>
</tr>
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<tbody>
<tr>
<td>PV Diameter Decrease</td>
<td></td>
</tr>
<tr>
<td>1 to 25%</td>
<td>168 (43.9%)</td>
</tr>
<tr>
<td>26 to 50%</td>
<td>24 (6.3%)</td>
</tr>
<tr>
<td>&gt; 50%</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>PV Diameter Increase</td>
<td></td>
</tr>
<tr>
<td>0 to 25%</td>
<td>180 (47.0%)</td>
</tr>
<tr>
<td>26 to 50%</td>
<td>9 (2.3%)</td>
</tr>
<tr>
<td>&gt; 50%</td>
<td>2 (0.5%)</td>
</tr>
</tbody>
</table>
Table 5. VGLA-Related Complications

<table>
<thead>
<tr>
<th>Complication Type</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phrenic Nerve Injury</td>
<td>5 (2.5%)</td>
</tr>
<tr>
<td>Transient Ischemic Attack</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Atrio-esophageal Fistula</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>3 (1.5%)</td>
</tr>
<tr>
<td>Minor</td>
<td>7 (3.5%)</td>
</tr>
</tbody>
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Figure Legend:

**Figure 1.** Procedural Parameters as a Function of Operator Experience. Procedural parameters are compared for the first 15 procedures performed by operators vs. cases beyond the first 15 (i.e. operators served as their own controls). Procedure time, ablation time, and fluoroscopy time all improved with increased experience.
Procedural Parameters vs. Operator Experience

- Procedure Time: 
  - ≤15 (N=139): 209±60 minutes
  - >15 (N=61): 179±40 minutes
  - P = 0.0005

- Ablation Time: 
  - ≤15 (N=139): 115±39 minutes
  - >15 (N=61): 97±28 minutes
  - P = 0.001

- Fluoroscopy Time: 
  - ≤15 (N=139): 37±22 minutes
  - >15 (N=61): 19±8 minutes
  - P < 0.0001
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