Feasibility of Circumferential Pulmonary Vein Isolation Using a Novel Endoscopic Ablation System

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Background—Pulmonary vein isolation (PVI) is an established treatment option for patients with drug refractory paroxysmal atrial fibrillation. A novel compliant endoscopic ablation system housing a 980-nm-diode laser allows for discrete point-by-point ablation enabling a true circumferential ablation line design. We sought to determine the feasibility and safety of a circumferential ablation using endoscopic ablation system.

Methods and Results—Thirty patients (17 female; mean age, 58 ± 9 years) with a median paroxysmal atrial fibrillation history of 3 years (range, 1 to 17 years) were treated. PVI was achieved in 114 of 116 (98%) PVs (4 left common PVs), thereby achieving simultaneous PVI for separate ipsilateral PVs in 19 of 26 (73%) left PVs and 6 of 30 (20%) right PVs. The total procedure time was 250 ± 62 minutes. Procedure time decreased from 310 ± 59 to 220 ± 37 minutes (P = 0.0001) between the first 10 and the last 20 cases. Mean fluoroscopy time was 30 ± 18 minutes. Twenty-seven patients underwent postoperative endoscopy showing no or minimal thermal lesions in the esophagus in 21 (78%) and 2 (7%), respectively. In 4 (15%) patients, an esophageal ulceration was found that healed without sequelae. One pericardial tamponade and 1 right-sided phrenic nerve palsy occurred. During a median follow-up of 168 days (113 to 203 days; q1-q3), 24 of 30 patients (80%) remained free of atrial fibrillation recurrence.

Conclusions—Circumferential PVI using the novel compliant endoscopic ablation system was feasible in the majority of left PVs and minority of right PVs accompanied by a complication rate comparable to established approaches. To minimize the risk for thermal esophageal injury temperature monitoring is recommended. (Circ Arrhythm Electrophysiol. 2010;3:481-488.)

Key Words: balloon • fibration • ablation

Pulmonary vein isolation (PVI) is the cornerstone therapy for drug-refractory paroxysmal atrial fibrillation (PAF).1 Recent randomized trials demonstrated the superiority of a wide circumferential ablation line design compared with segmental PVI using radiofrequency current ablation.2 Current balloon technologies using cryothermal, ultrasound, or the hot balloon are designed to separately isolate each PV, which may result in a more distal level of isolation.3–6 However, simultaneous isolation of ipsilateral pulmonary veins using balloon catheters achieving a proximal circumferential ablation lesion have been described.7–8

Clinical Perspective on p 488

The feasibility of PVI using an endoscopic ablation system (EAS) designed as a balloon catheter housing a near infrared diode laser generator was recently demonstrated in a multicenter trial.9 However, with this first-generation EAS, successful energy deployment was cumbersome because of significant technological limitations. First, the noncompliance of the first-generation EAS did not provide optimal balloon to tissue contact resulting in overlapping blood. Second, because of the relatively large ablative laser arc size, that covered 90° to 120° of a circle it could not be precisely targeted to the suboptimal exposed tissue. Both factors increased the risk for thrombus formation during laser energy applications. As a consequence, individual PVI was achieved acutely in only 91% of PVs, resulting in a chronic clinical success rate of 60% after 12 months.

The novel EAS (CardioFocus, Inc, Marlborough, Mass) has become available with an adjustable compliant balloon and a decreased laser arc size to allow for discrete point-by-point ablation and a configurable ablation line design (Figure 1). We determined the feasibility and safety of such a flexible circumferential ablation using EAS in patients with drug-refractory PAF.

Methods

The study protocol was approved by the Hamburg ethic committee (study number PV 3252). All patients gave written informed consent before inclusion.
Inclusion and Exclusion Criteria
Eligible patients were 18 to 70 years of age, with PAF unresponsive to at least 1 antiarrhythmic drug (class I to III) and who had not undergone a previous PVI attempt. At least 2 AF episodes had to be documented within the past 6 months. Left atrial (LA) size had to be <50 mm and the maximal allowed PV diameter was 32 mm. All patients had to be willing to comply with the study protocol for at least 12 months.

The presence of structural heart disease with reduced left ventricular function <30% or valvular dysfunction greater than class II was a separate exclusion criterion.

Preprocedural Imaging
All patients underwent transthoracic echocardiography before the procedure to determine LA dimensions and valve patency. Transesophageal echocardiography was performed the day before the procedure to rule out LA thrombus.

In addition, LA magnetic resonance angiography was performed before and 3 months after the ablation to assess PV geometry and size and to screen for PV stenosis.

The Endoscopic Ablation System
The EAS consists of a nonsteerable, compliant balloon catheter with a range of diameters that allows treatment of PVs as small as 9 mm and as large as an average PV diameter of 32 mm (Figure 1). After introduction into the LA through a steerable 12F sheath, it is filled and continuously flushed with D2O for cooling purposes. The central catheter shaft houses a 2F fiberoptic endoscope that enables direct visualization of the PV antrum once the balloon has been inflated. An aiming beam can be directed to the desired ablation zones via a second fiber. Laser energy can also be delivered through this same fiber from a 980-nm laser diode source.

Ablation power is adjustable in 10 defined steps from 5.5 W to 18 W. Applications last from 20 to 30 seconds, depending on preselected power. The location of the laser projection and the resulting ablation lesions can be moved independently from the balloon catheter itself and are deployed in a point-by-point fashion to create a customized circumferential line design. Each individual ablation lesion covers 30° of a circle. To increase the likelihood of a transmural contiguous lesion set, the individual lesions were overlapped by 30% to 50%.

Using customized software, all endoscopic images were stored and reviewed instantaneously on a separate screen to confirm overlap and to detect potential gaps in the circumferential ablation line.

Both the aiming and the laser beams may be rotated and advanced/retracted, freely allowing for an anatomically flexible lesion design. The balloon size may also be adjusted to the individual PV anatomy to optimize sealing and maximize the area of tissue exposure to the laser arc.

For orientation, the central catheter shaft is equipped with a radiopaque L-shaped marker that allows correlation of the endoscopic with the fluoroscopic image.

Electrophysiological Procedure
The procedures were performed under sedation using boluses of midazolam and fentanyl as well as continuous infusion of propofol 1%.

After placing 6F decapolar catheters into the coronary sinus and along the His bundle region, 2 transseptal punctures were performed using a modified Brockenbrough technique to introduce 2 8F sheaths (SL1; St Jude Medical, Minnetonka, Minn) into the LA. Thereafter, heparin boluses were repeatedly administered to maintain activated clotting time between 300 and 350 seconds. Selective PV angiography was performed to identify the PV ostia. A spiral catheter (Biosense Webster, Inc, Diamond Bar, Calif) was placed at the PV ostium to record PV potentials using a conventional computerized EP-system (EP Workmate, St Jude Medical).

An esophageal temperature probe (SensiTherm, St Jude Medical) was inserted transorally to continuously monitor esophageal temperature during ablation. If esophageal temperature exceeded 38.5°C energy delivery was terminated.

Importantly, during energy delivery at the RPV ostia, continuous phrenic nerve stimulation with maximal stimulation output (20 mA, 5 ms) was performed from a diagnostic catheter in the superior caval vein. If loss of capture was observed, energy delivery was instantaneously terminated.

PVI Using EAS
To introduce the EAS balloon catheter to the LA, 1 SL1 sheath was exchanged with a steerable 12F transseptal sheath. The EAS balloon was maneuvered to the respective PV ostium facilitated by intracardiac echocardiography (ViewFlex, St Jude Medical). Optimal PV occlusion was attempted by varying balloon inflation pressure to expose a circumferential ring of atrial myocardium around the PV ostium. Because the catheter shaft obscures one fifth of the circumference, catheter rotation is required to complete ablation at a particular PV.

The ablation line was designed as a figure of eight at the ipsilateral PV ostia. Two incomplete circles connecting to each other at the PV carina were created in an attempt to achieve simultaneous ipsilateral...
PVI (Figure 2A through 2D): First, a circumferential ablation line was created around the superior PV, leaving an intentional gap at the medial carina. Second, the EAS was positioned at the inferior PV ostium aiming at perfect occlusion. Simultaneously, a spiral mapping catheter was placed at the superior PV ostium to obtain online PV recordings during laser applications at the inferior PV ostium. In the case of completion of the circumferential ablation line, online electric PVI was documented by the spiral catheter placed at the superior PV ostium. Likewise, electric PVI of the inferior PV was assessed thereafter.

To attempt an ipsilateral PVI approach, partial or complete visualization of the inferior PV from a superior PV balloon position or vice versa was required. If both ipsilateral PVs could not be visualized simultaneously, ipsilateral PVs were targeted separately and isolated individually. Furthermore, if instantaneous PVI after completion of 2 incomplete circular lines failed, ipsilateral PVs were finally isolated separately.

Notably, the spiral catheter was not kept at the respective PV ostium during individual circular isolation because its shaft impeded total PV occlusion. After completion of the ablation circle, the balloon was deflated to assess LA-to-PV conduction with the spiral catheter.

If individual electric PVI was not achieved after a single ablation, circle gap mapping was performed. Therefore, the spiral catheter was placed distally to the inflated EAS to visualize electric PVI online during lasing. The spiral catheter shaft was positioned opposite to the presumed gap to avoid imperfect PV sealing at the desired ablation site.

The end point for ablation was complete electric isolation of all PVs, assessed by a spiral catheter positioned at the PV ostium 30 minutes after the last energy application.

Postprocedural Care
After echocardiographic exclusion of pericardial effusion, oral anticoagulation with phenprocoumon was resumed, targeting an INR of 2 to 3 for at least 3 months. Low-molecular-weight heparin was administered in a therapeutic dose until a therapeutic INR of 2 to 3 was reached. Previously ineffective antiarrhythmic drug therapy was continued for 30 days.

Study End Points and Follow-Up
The primary objective of this study was to assess safety, feasibility, and efficacy of circumferential PVI using the novel EAS. The
primary safety end point was defined as the occurrence of periprocedural and postprocedural complications such as major bleeding requiring transfusion, pericarditis, and Q-wave myocardial infarction within 1 week; damage of cardiac valves, cardiac tamponade, cerebral vascular accident, or coronary artery spasm within 1 month; phrenic nerve palsy or atrooesophageal fistula within 6 months; or death or PV stenosis within 12 months after EAS treatment. The primary efficacy end point was freedom from AF lasting longer than 1 minute between 90 and 360 days after ablation off antiarrhythmic drugs. The study protocol included a 3-month blanking period.

A telephonic follow-up was carried out 30 days after ablation. At day 90, patients attended an outpatient visit including 24-hour Holter ECG and MRI to exclude PV stenosis. All antiarrhythmic medication was stopped at day 90 unless another medical condition (eg, β-blocker to treat hypertension) prohibited its cessation. Patients were equipped with a transtelephonic ECG monitor to transmit weekly ECG or in the case of symptoms suggestive of arrhythmia recurrence.

Repeat Procedures
In the case of AF recurrence, a repeat procedure was performed according to the patient’s symptoms. To assess the anatomic gap location and the extent of the ablation lesion, repeat procedures were carried out using an electroanatomical mapping system. The method of electroanatomical mapping and circumferential PVI using irrigated radiofrequency current ablation was previously described in detail. In brief, after double transseptal puncture, an LA electroanatomical map (CARTO, Biosense Webster) was acquired and tagged on the electroanatomical map according to fluoroscopic and electric information. PV reisolation was accomplished using irrigated radiofrequency current ablation.

Statistical Analysis
Mean ± standard deviation data were used to describe continuous variables with normal distribution; otherwise, median and interquartile ranges were used. For diagnostic parameters, the absolute and relative frequencies were counted. The unpaired t test was used to compare mean procedure and fluoroscopy times for the first 10 and last 20 patients.

Results
Thirty patients (17 female; mean age, 58 ± 9 years) with a median PAF history of 3 years (range, 1 to 17 years) refractory to a median of 2 (range, 1 to 4) antiarrhythmic drugs were enrolled in the study (Table). The mean LA diameter was 42 ± 3 mm, and all patients had a normal left ventricular ejection fraction. Twenty patients had well-controlled arterial hypertension and 2 patients had a history of stable coronary artery disease.

Mean PV size was 16 ± 3 mm, 15 ± 3 mm, 16 ± 2 mm, and 15 ± 2 mm for the right superior (RS), right inferior (RI), left superior (LS), and left inferior (LI) PV, respectively. Four patients presented with a left common (LC) PV with a mean diameter of 24 ± 4 mm. In 3 patients, a right middle (RM) PV with a mean diameter of 8 ± 2 mm was detected in the magnetic resonance angiography.

PVI With EAS
A total of 116 PVs (4 patients with LCPV) were treated with the EAS. The end point of PVI could be achieved in 114 of 116 (98%) PVs. Remarkably, all LCPVs were successfully isolated. In patient 10, electric isolation of the RIPV was not attempted because of a technical endoscope failure toward the procedure end. In patient 18, ablation at the RSPV was aborted because of phrenic nerve palsy.

In 52 separate LPV ostia, simultaneous PVI of ipsilateral LPVs was achieved in 38 (73%; Figure 2A through 2D and Figure 3). In all simultaneous ipsilateral isolations, electric PVI was documented by a spiral catheter in the LSPV. Electric isolation of the LIPV was documented after deflation of the balloon.

In 4 patients, the LIPV could not be visualized from the LSPV ostium; therefore simultaneous ipsilateral PVI was not attempted but achieved sequentially.

In addition, in 3 patients, simultaneous ipsilateral PVI was attempted but not achieved despite optical connection of the 2 ablation circles. The 6 PVs of the latter 3 patients were ultimately isolated sequentially.

The median number of laser applications for the LPVs was 42 (q1-q3; 31 to 58), 37 (27 to 55), and 63 (55 to 68) for the LSPV, LIPV, and LCPV, respectively.
At the RPVs, 12 PVs were simultaneously visualized and isolated (Figure 3B). In all simultaneous ipsilateral isolations, electric PVI was documented by a spiral catheter in the RSPV. Electric isolation of the RIPV was documented after deflation of the balloon.

In the remaining 48 RPVs, simultaneous visualization was not achieved and sequential PVI was pursued. This resulted in successful separate isolation of 46 RPVs. In 1 patient, the RSPV was not isolated because of phrenic nerve palsy and in 1 patient RIPV was not achieved because of an endoscope failure. The RMPVs were included in the circumferential ablation line in 2 patients and within the ablation circle around the RSPV in 2 patients, respectively. The median number of laser applications was 32 (23 to 38) and 32 (25 to 41) for the RSPV and RIPV, respectively.

**Gap Mapping**

In 12 of 60 PVs (20%) with an individual isolation attempt, PVI was not achieved after a single ablation circle and mapping was performed to determine the conduction gap. All PVs were successfully isolated with a median of 6 (q1-q3; 4 to 6) laser applications after placement of a spiral catheter distal to the EAS (Figure 4).

The total procedure time including a 30-minute waiting period after the last PVI was 250 ± 62 minutes. Notably, a significant shortening of procedure time from 310 ± 59 to 220 ± 37 minutes (P=0.0001, unpaired t test) was observed between the first 10 and the last 20 cases (Figure 5). The interventions were performed by 2 different operators. The mean fluoroscopy time was 30 ± 18 minutes. Similarly, the fluoroscopy time for the last 20 patients was significantly shorter than for the first 10 patients (23 ± 2 versus 47 ± 6 minutes; P=0.0001).

**Esophageal Temperature and Postoperative Endoscopy**

In 18 of 30 patients (60%), the laser applications had to be interrupted at least once after the esophageal temperature had exceeded the predefined level of 38.5°C. The circumferential ablation line was continued more proximal or with less energy. In none of the patients, esophageal temperature rises prevented effective PVI.

The maximal esophageal temperature observed was 45.1°C. Because of a technical failure of the temperature monitoring system, the operator was not alerted that the preset temperature threshold had been exceeded and as a result energy delivery continued.

Twenty-seven patients underwent postoperative endoscopy 48 hours after the ablation. In 21 (78%) and 2 (7%), no or minimal thermal lesions were found, respectively. However, in 4 (15%) patients, an esophageal ulceration was found. After intravenous application of proton-pump inhibitors, ulcerations fully recovered demonstrated by repeat endoscopy after 6 ± 1 day. The mean esophageal temperatures were 38.7 ± 1.2°C, 39.5 ± 0.7°C, and 40.6 ± 3°C in the group with no, minimal lesions, or ulceration, respectively.
Complications
Periprocedural complications occurred in 2 patients. Patient 5 had an LA perforation requiring surgical intervention. The most likely cause was mechanical trauma by the steerable sheath that whipped to the LA roof after the deflated balloon catheter had been retracted into the sheath from the LIPV and the sheath did not maintain its deflected curve. The system is not constructed as an “over-the-wire” device that would help to guide both the balloon and the sheath. After surgical intervention, the patient fully recovered.

In patient 16, phrenic nerve palsy occurred while lasing at the RSPV. During phrenic nerve pacing, the stimulation catheter dislodged and energy deployment was not immediately terminated. After the energy application was completed, phrenic nerve palsy was already present. During follow-up, the patient remained asymptomatic, but nerve function had not recovered at the 3-month follow-up visit.

Importantly, no PV stenosis was detected during MRI at 3-month follow-up that had been completed by 26 patients. Mean PV size was unchanged as compared with the preprocedural MRI (LSPV, P=0.33; LIPV, P=0.43; LCPV, P=0.39; RSPV, P=0.42; and RIPV, P=0.42; paired t test).

Follow-Up
At hospital discharge, 15 of 30 patients continued the previously ineffective antiarrhythmic drug (class I or sotalol), including amiodarone in 2 patients. At the 90-day follow-up visit, only 8 of 26 patients were still taking antiarrhythmic drugs, including amiodarone in 2 patients. All antiarrhythmic drugs were stopped at the 90-day follow-up visit.

During a median follow-up of 168 days (113 to 203 days; q1-q3) after the procedure, 24 of 30 patients (80%) remained free of any symptomatic AF recurrence lasting >1 minute after a single procedure off antiarrhythmic drugs. Three of the 6 patients with AF recurrences were well controlled on the previously ineffective class IC antiarrhythmic drug. Two patients underwent a repeat procedure and 1 patient refused the repeat procedure.

Repeat Procedures
In 2 patients, repeat ablation was performed 126 and 133 days after the index procedure. In patient 10, all PVs exhibited electric reconnection. In this patient, the RIPV had not been isolated during the index procedure. Therefore a complete circumferential ablation line was deployed for simultaneous RPVI. The LPVs demonstrated a single conduction gap at the anterior myocardial ridge separating the PVs from the left atrial appendage. In patient 8, the RSPV exhibited permanent PVI (Figure 6). The RIPV was reisolated at a posterior-superior conduction gap with a single irrigated radiofrequency current ablation application. The LPVs that were initially isolated simultaneously were reisolated at an anterior conduction gap between the LPVs with a single energy application.

Discussion
In the present study, the feasibility, safety, and efficacy of circumferential PVI using the novel EAS were assessed. The major findings were that (1) 98% of all PVs were successfully isolated; (2) circumferential PVI is feasible and results in simultaneous isolation of ipsilateral PVs in 19 of 26 (73%) of cases for the LPVs and 6 of 30 (20%) of cases for the RPVs; (3) simultaneous visualization of the PV ostial anatomy and electric information using a spiral catheter is a viable way of gap mapping; and (4) esophageal temperature monitoring is recommended to avoid potentially serious thermal injury.

Pulmonary Vein Isolation
Electric PVI is the desired end point of any AF ablation procedure targeting the PVs as recommended by the most recent HRS/EHRA/ECAS consensus statement. However, there is ongoing debate on whether circumferential PVI including a substantial portion of the antral musculature is superior to a more distal segmental PVI approach. Current balloon technologies are designed to target each PV individually resulting in a more distal level of PVI, although simultaneous PVI of ipsilateral LPVs (“cross-talk”) has been described using the cryotherm and the high-intensity focused ultrasound balloon.

Circumferential PVI by a point-by-point ablation approach using radiofrequency current is still challenging because of the complex LA anatomy and the need for permanent transmural lesions. Therefore, 3D mapping systems, additional imaging modalities such as intracardiac echocardiography, and contact force–sensing technologies were suggested to improve safety and success. Current balloon technologies may ease navigation but offer only limited flexibility in terms of ablation line design. First,
both the cryothermal balloon and the high-intensity focused ultrasound balloon are not adjustable to the individual PV size, eventually affording multiple balloon catheters during a single procedure.\textsuperscript{3,14} Second, energy titration is not possible since both balloon catheters work with binary (on/off) energy modes. Third, lesion placement is inflexible because of its restriction to a fixed sonication ring or the whole balloon surface.

The novel EAS by its implemented endoscope offers the ability to directly visualize the substrate for ablation superseding the need for additional imaging. In comparison to the above-mentioned balloons, its size is adjustable to the individual anatomy in a broad range. This allows for treatment of virtually any PV with a single device. In conjunction with the flexible lesion deployment, the operator has the freedom to create the preferred ablation line design. Last, the ability to titrate energy may potentially decrease injury to adjacent structures such as the esophagus and the phrenic nerve as well as increasing success by applying high ablation energy at the myocardial ridge separating the LPVs from the LA appendage.

As demonstrated, even a circumferential ablation line including both ipsilateral PVs is feasible in a subset of patients. However, this approach is limited by the individual PV anatomy and the lack of consistent lesion visualization. Because endoscopic information is only 2-dimensional, it remains challenging to assess the level of the ablation lines in relationship to the PV ostium. Future innovations improving lesion visualization could help to facilitate this approach. Finally, it remains to be assessed whether a circumferential line design using EAS is superior to an individual PV encircling.

In both patients who underwent a repeat ablation, an anterior gap in the circumferential ablation line around the LPVs was present. This “gap pattern” resembles the location pattern of cryothermal balloon procedures.\textsuperscript{15} Future trials will have to determine the optimal dosing to create permanent lesions without adverse effects.

**Gap Mapping**

The lack of electric information from the PVs at the time of ablation is a major shortcoming of the EAS technology. It was not designed to perform simultaneous mapping and ablation using the ipsilateral ablation approach. In the present study, we developed a technique to use the EAS in conjunction with a distally positioned spiral catheter. This method facilitated gap mapping and allowed for online visualization of the ablation effect. It could be speculated that this might have reduced the number of ineffective ablation lesions.

**Esophageal Temperature Monitoring and Thermal Injury**

It is well known that thermal esophageal injury occurs in a substantial number of patients undergoing radiofrequency current–guided AF ablation.\textsuperscript{16} In animal models, it was demonstrated that thermal esophageal injury in conjunction with gastric acid reflux might herald the development of atrioesophageal fistula.\textsuperscript{17} To minimize the risk of thermal injury, the use of esophageal temperature monitoring was advocated.\textsuperscript{18} As expected, the use of near infrared laser energy occasionally resulted in significant heating and mucosal damage of the adjacent esophagus. The present data suggest that the risk for thermal injury is low if esophageal temperature does not exceed 38.5°C. However, in approximately one third of patients, the esophageal temperature rose beyond 39°C despite cessation of energy delivery at 38.5°C, resulting in esophageal ulcerations in 15% of patients. There was a trend toward higher esophageal temperatures resulting in more severe mucosal damage as known from other energy sources.\textsuperscript{19} Therefore, temperature monitoring should be considered an indispensable prerequisite for PVI procedures based on EAS use. The patient number in this study is certainly too low to determine the optimal esophageal cutoff temperature and to prove safety in terms of atrioesophageal fistula formation.

**Safety and Long-Term Follow-Up**

The use of EAS for PVI was feasible, with a reasonable safety profile. A mechanical LA perforation occurred that was attributable to incautious use rather than to device design. In the present study, only 1 phrenic nerve palsy was observed that had not recovered at 3-month follow-up. The exact incidence of phrenic nerve palsies after EAS treatment remains to be determined in large-scale clinical trials but appears to be rather low compared with other balloon technologies.\textsuperscript{7,8,14}

No PV stenosis was detected at the 3-month follow-up visit. Recently published data on PV stenoses from the updated worldwide survey showed that nowadays, PV stenosis requiring intervention has become a rare complication of AB ablation.\textsuperscript{20}

The present efficacy data compare with previously published data after irrigated radiofrequency current ablation procedures.\textsuperscript{10} However, the patient cohort was small, and future multicenter, randomized trials must assess EAS efficacy and safety in comparison to other energy sources.

**Future Directions**

Reasonable procedure times were observed after passing a rather short learning curve. The latter might be longer for operators with less balloon experience.

It might be desirable to redesign the EAS as an over-the-wire device to enhance the safety profile and to ease navigation.

To further shorten procedure times, it would be desirable to provide a means to vary the arc size, which should be feasible with larger contact areas achieved with the compliant balloon. This could reduce the number of laser applications to accomplish a circular ablation line.

**Conclusion**

Circumferential PVI using the novel, compliant EAS was feasible in the majority of LPVs and a minority of RPVs accompanied by a complication rate comparable to established approaches. Visualization of electric information using a spiral catheter is feasible during circumferential PVI and for gap mapping. To minimize the risk for thermal esophageal injury, temperature monitoring is recommended.

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