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

Schmidt et al.; Circumferential Pulmonary Vein Isolation with Endoscopic Balloon

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Abstract:

Background: Pulmonary vein isolation (PVI) is an established treatment option for patients with drug refractory paroxysmal atrial fibrillation (PAF). A novel compliant endoscopic ablation system (EAS) housing a 980nm 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 EAS.

Methods and Results: Thirty patients (17 female, mean age 58 ± 9 years) with a median PAF history of 3 years (range 1-17 years) were treated. PVI was achieved in 114/116 (98%) PVs (4 LCPVs), thereby achieving simultaneous PVI for separate ipsilateral PVs in 19/26 (73%) LPVs and 6/30 (20%) RPVs.

The total procedure time was 250 ± 62 min. Procedure time decreased from 310 ± 59 to 220 ± 37 min (p = 0.0001) between the first 10 and the last 20 cases. Mean fluoroscopy time was 30 ± 18 min.

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 one right sided phrenic nerve palsy occurred.

During a median follow-up of 168 days (113-203 days; q1-q3) 24/30 patients (80%) remained free of AF recurrence.

Conclusion: Circumferential PVI using the novel compliant EAS was feasible in the majority of LPVs and minority of RPVs accompanied by a complication rate comparable to established approaches. To minimize the risk for thermal esophageal injury temperature monitoring is recommended.

Key words: Balloon, Fibrillation, Ablation
INTRODUCTION

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 to 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).

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 multi-centre trial (9). However, with this first generation EAS successful energy deployment was cumbersome due to significant technological limitations. First, the non-compliance of the first generation EAS did not provide optimal balloon to tissue contact resulting in overlapping blood. Second, due to the relatively large ablative laser arc size, that covered 90-120° 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, MA, USA) 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.
PATIENTS AND METHODS

The study protocol was approved by the Hamburg ethic committee (study number PV 3252). All patients gave written informed consent prior to inclusion.

Inclusion and exclusion criteria

Eligible patients were aged 18 to 70 years with PAF unresponsive to at least one antiarrhythmic drug (class I-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 less than 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 >II° was a separate exclusion criterion.

Pre-procedural imaging

All patients underwent transthoracic echocardiography prior to the procedure in order 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 prior to 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 non-steerable, 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 via a steerable 12F sheath it is filled and continuously flushed with D₂O for cooling purposes. The central catheter shaft houses a 2 F
fiber optic endoscope which 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 via this same fiber from a 980 nm, laser diode source.

Ablation power is adjustable in ten defined steps from 5.5 W to 18 W. Applications last from 20-30 secs depending on pre-selected 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. In order to increase the likelihood of a transmural contiguous lesion set, the individual lesions were overlapped by 30-50%.

Using customized software all endoscopic images were stored and reviewed instantaneously on a separate screen in order 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 in order 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 two 8F sheaths (SL1; St. Jude Medical) into the LA. Thereafter, heparin boluses were repeatedly administered to maintain activated clotting time between 300 and 350 sec. Selective PV angiography was performed to identify the PV ostia. A spiral catheter (Biosense Webster, Inc., Diamond Bar, CA, USA) was placed at the PV ostium to record PV potentials using a conventional computerized EP-system (EP workmate, St. Jude Medical, USA).

An esophageal temperature probe (SensiTherm, St. Jude Medical) was inserted trans-orally 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 (20mA, 5ms) was performed from a diagnostic catheter in the superior caval vein. If loss of capture was observed, energy delivery was instantaneously terminated.

**Pulmonary Vein Isolation using EAS**

In order to introduce the EAS balloon catheter to the LA one 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 in order to expose a circumferential ring of atrial myocardium around the PV ostium. Since 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-D): 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 case of completion of the circumferential ablation line online electrical PVI was documented by the spiral catheter placed at the superior PV ostium. Likewise, electrical PVI of the inferior PV was assessed thereafter. In order 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 two 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 electrical PVI was not achieved after a single ablation circle gap mapping was performed. Therefore, the spiral catheter was placed distally to the inflated EAS in order to visualize electrical 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 endpoint for ablation was complete electrical 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 2-3 for at least 3 months. Low-molecular weight heparin was administered in a therapeutic dose until a therapeutic INR of 2-3 was reached. Previously ineffective antiarrhythmic drug therapy was continued for 30 days.
Study endpoints 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 endpoint was defined as the occurrence of peri- and postprocedural complications such as major bleeding requiring transfusion, pericarditis and q wave myocardial infarction within one week, damage of cardiac valves, cardiac tamponade, cerebral vascular accident or coronary artery spasm within one month, phrenic nerve palsy or atrio-esophageal fistula within 6 months or death or pulmonary vein stenosis within 12 months after EAS treatment.

The primary efficacy endpoint was freedom from AF lasting longer than 1 minute between 90 and 360 days post ablation off of antiarrhythmic drugs. The study protocol included a 3 months blanking period.

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

Repeat procedures

In case of AF recurrence a repeat procedure was performed according to the patient’s symptoms. In order to assess the anatomical 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 (10). In brief, after double transseptal puncture a LA electroanatomical map (CARTO, Biosense Webster, Diamond Bar, CA, USA) was
acquired and selective PV angiographies were performed. Electrical PV-LA re-connection was assessed using a spiral catheter. The PV ostia were tagged on the electroanatomical map according to fluoroscopic and electrical information. PV re-isolation was accomplished using irrigated radiofrequency current ablation.

Statistical Analysis

Data mean ± standard deviation was used to describe continuous variables with normal distribution; otherwise median and range or interquartile range were used. For diagnostic parameters the absolute and relative frequency were counted. The unpaired t test was used to compare mean procedure and fluoroscopy times for the first ten and last twenty patients.

RESULTS

Thirty patients (17 female, mean age 58 ± 9 years) with a median PAF history of 3 years (range 1-17 years) refractory to a median of 2 (range 1-4) antiarrhythmic drugs were enrolled in the study (Table 1). The mean LA diameter was 42 ± 3 mm and all patients had a normal left ventricular ejection fraction. Twenty patients suffered from 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, 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 three patients a right middle (RM) PV with a mean diameter of 8 ± 2 mm was detected in the magnetic resonance angiography.

Pulmonary vein isolation with EAS

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

In 52 separate LPV ostia simultaneous PVI of ipsilateral LPVs was achieved in 38 (73%; Figure 2A-D and 3). In all simultaneous ipsilateral isolations electrical PVI was documented by a spiral catheter in the LSPV. Electrical 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 two 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; 31-58), 37 (27-55) and 63 (55-68) for the LSPV, LIPV and LCPV, respectively.

At the RPVs, twelve PVs were simultaneously visualized and isolated (Figure 3B). In all simultaneous ipsilateral isolations electrical PVI was documented by a spiral catheter in the RSPV. Electrical 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 one patient the RSPV was not isolated because of phrenic nerve palsy and in one patient RIPV was not achieved due to 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 (23-38) and 32 (25-41) for the RSPV and RIPV, respectively.
Gap mapping

In 12/60 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; 4-6) 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 min. Notably, a significant shortening of procedure time from 310 ± 59 to 220 ± 37 min (p = 0.0001, unpaired t-test) was observed between the first ten and the last 20 cases (Figure 5).

The interventions were performed by two different operators. The mean fluoroscopy time was 30 ± 18 min. Similarly, the fluoroscopy time for the last 20 patients was significantly shorter than for the first ten patients (23 ± 2 versus 47 ± 6 min; p = 0.0001).

Esophageal temperature and postoperative endoscopy

In 18/30 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. Due to 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
12 days. 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

Peri-procedural complications occurred in 2 patients. Patient #5 suffered from a 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 3 months follow-up visit.

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

Follow-up

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

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

**Repeat procedures**

In two patients a repeat ablation was performed 126 and 133 days after the index procedure. In patient #10 all PVs exhibited electrical 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 re-isolated at a posterior-superior conduction gap with a single irrigated radiofrequency current ablation application. The LPVs that were initially isolated simultaneously were re-isolated 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 19/26 (73%) of cases for the LPVs and 6/30 (20%) of cases for the RPVs; 3) simultaneous visualization of the PV ostial anatomy and electrical information using a spiral catheter is a viable way of gap mapping; 4) esophageal temperature monitoring is recommended to avoid potentially serious thermal injury.
Electrical PVI is the desired endpoint of any AF ablation procedure targeting the PVs as recommended by the most recent HRS/EHRA/ECAS consensus statement (1). 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 (2;11). Current balloon technologies are designed to target each PV individually resulting in a more distal level of PVI (5;6), although simultaneous PVI of ipsilateral LPVs (“crosstalk”) has been described using the cryothermal and the HIFU balloon (7;8).

Circumferential PVI by a point-by-point ablation approach using radiofrequency current is still challenging due to the complex LA anatomy and the need for permanent transmural lesions. Therefore, 3D mapping systems, additional imaging modalities like intracardiac echocardiography and contact force sensing technologies were suggested to improve safety and success (10;12;13).

Current balloon technologies may ease navigation but offer only limited flexibility in terms of ablation line design. Both the cryothermal balloon and the HIFU balloon are not adjustable to the individual PV size, eventually affording multiple balloon catheters during a single procedure (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. Since, endoscopic information is only two 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, if 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 (15). Future trials will have to determine the optimal dosing in order to create permanent lesions without adverse effects.

**Gap mapping**

The lack of electrical 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 this 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 on-line 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 (16). In animal models it was
demonstrated that thermal esophageal injury in conjunction with gastric acid reflux might herald the development of atrio-esophageal fistula (17). In order to minimize the risk of thermal injury the use of esophageal temperature monitoring was advocated (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 towards higher esophageal temperatures resulting in more severe mucosal damage as known from other energy sources (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 cut-off temperature and to prove safety in terms of atrio-esophageal 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 this study only one 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 seems to be rather low compared to other balloon technologies (7;8;14).

No PV stenosis was detected at 3 months follow-up visit. Recently published data on PV stenoses from the updated world-wide survey showed, that nowadays PV stenosis requiring intervention has become a rare complication of AF ablation (20).

The present efficacy data compares to previously published data after irrigated radiofrequency-current ablation procedures (10). However, the patient cohort was small and
future multi-centre randomized trials need to 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.

In order 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 electrical 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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**Conflict of Interest Disclosures:** KH Kuck received a research grant and speaker's honoraria by CardioFocus.
References:


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<td>20 (66)</td>
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<td>LA size [mm]</td>
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**Table 1**: Patient demographics. Data is given as mean ± SD unless otherwise indicated. PAF: paroxysmal atrial fibrillation; AAD: antiarrhythmis drug; LA: left atrium.
Figure Legends:

Figure 1: Functioning of the novel EAS. Left panel: Schematic Drawing of the EAS with its technical components. Right panel: Inflated EAS shown from its tip. Note the spot-like laser arc size (30° of a circle). This allows for discrete point-by-point ablation. The previous generation EAS was equipped with a laser arc covering 90-120° of a circle.

Figure 2: Simultaneous pulmonary vein isolation at the left PVs. A) Fluoroscopic view (left anterior oblique 40°) of the balloon catheter (EAS) at the left superior PV (LSPV). Diagnostic catheter placed in high right atrium (HRA) and coronary sinus (CS). Esophageal temperature probe (Eso). Spiral catheter at left inferior PV ostium (LIPV). Schematic drawing of the ablation line design. Green bars represent ablation spots. Dotted circle represents spiral catheter in LIPV. B) Fluoroscopic view (left anterior oblique 40°) of the balloon catheter (EAS) at the left inferior PV (LIPV). Schematic drawing with complete circumferential ablation line. C) Endoscopic View to LPVs. D) Electrograms recorded by a spiral catheter in the LSPV during ablation at the LIPV. Arrows indicate absence of PV spike after complete PVI.

Figure 3: Flowchart of pulmonary vein isolation patterns. A) Left PVs (LPVs); B) right PVs (RPVs). LCPV: left common PV. RSPV: right superior PV. RIPV: right inferior PV. Sim iso: simultaneous ipsilateral PVI; sep iso: separate PVI.

Figure 4: Gap mapping with simultaneous visualization of PV ostial anatomy and the electrogram.
Figure 5: Learning curve. A) Procedural time per patient. Dotted lines denote the interquartile range. B) Significant reduction of procedure time between the first ten patients and the last 20 patients (p=0.0001; unpaired t-test).

Figure 6: Electroanatomical voltage map of the left atrium during a repeat procedure in patient #8 in a posterior-anterior projection (PA; left) and a right anterior oblique (RAO) view. The white dots mark the PV ostium. Note the low-voltage area that is situated at the angiographically defined PV ostium (0.5 -1.5 mV abnormal myocardium displayed in color, >1.5 mV normal myocardium displayed in purple).
56 LPVs

4 LCPVs

4 LCPVs iso

44 LPVs visualized

52 LPVs with separate ostia

8 LPVs not visualized

38 LPVs iso sim

6 LPVs iso sep

8 LPVs iso sep
60 RPVs

12 RPVs visualized
- 12 RPVs iso sim

48 RPVs not visualized
- 46 RPVs iso sep
- 1 RSPV + 1 RIPV not iso
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