High anatomical accuracy of a novel high-resolution wide-band dielectric imaging system in cryoballoon-based ablation

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Abstract

Purpose: Recently, a novel cardiac imaging system based on a wide-band dielectric technology (KODEX-EPD) was introduced to guide catheter ablation. The aim of the study was to evaluate this 3D wide-band dielectric imaging system (WDIS) during cryoballoon (CB)-based atrial fibrillation (AF) ablation focusing on accuracy of pulmonary vein (PV)-anatomy.

Methods: In consecutive patients with symptomatic AF, CB-based ablation was performed in conjunction with the 3D WDIS. Selective PV-angiographies were performed, and 3D anatomy of the left atrium (LA) and PVs using the 3D WDIS was created. The ostial diameters of the ipsilateral right-sided and left-sided PVs and ostial diameters of the right-/left-sided upper/lower PVs demonstrated by selective angiographies were analyzed and compared to 3D WDIS-based PV visualization.

Results: In 65 patients (42/65 (65%) male, age 65 ± 9 years, 29/65 (45%) paroxysmal AF) a total of 260 PVs were identified. Median ostial PV-diameters for the ipsilateral left- and right-sided PVs were 38 [34; 43] and 37 [34; 40.3] mm when assessed fluoroscopically and 40 [35.7; 43] and 39 [35.0; 43] mm as demonstrated by 3D WDIS. There was no statistically significant difference between both methods regarding PV-diameter measurements. KODEX-EPD overestimated fluoroscopy measurements by 1.08 mm (95% limits of agreement of -1.93 mm and 4.1 mm).

Conclusion: The novel wide-band dielectric 3D-imaging system is feasible to create high-resolution images of cardiac structures during CB ablation procedures and accurately visualizes PV-anatomy.

KEYWORDS
atrial fibrillation, catheter ablation, CB-based PVI, novel imaging system, PV-visualization
1 | INTRODUCTION

Atrial fibrillation (AF) is the most common sustained arrhythmia and is associated with an increased risk of stroke, heart failure, and death. Catheter ablation aiming at pulmonary vein isolation (PVI) has become an established treatment option and provides not only encouraging clinical outcome data, but has also been shown to improve morbidity and mortality in patients with heart failure. While radiofrequency (RF) based PVI was considered the "gold standard" for a long time, balloon-based AF ablation—first and foremost cryoballoon (CB) based PVI—has moved into the foreground and has been shown to be non-inferior with regards to safety and outcome measures when compared to RF-ablation in patients with paroxysmal AF (PAF).

In contrast to RF-based AF ablation, which is usually supported by the use of 3D mapping systems, CB-based ablation procedures are mainly fluoroscopy guided. During CB-based PVI, selective angiography of the pulmonary veins (PVs) is the standard of care for identification of PV-ostia and—in combination with the injection of contrast medium—the assessment of catheter position and PV occlusion. Variable spatial orientation and variability of PV anatomy are important limitations of this imaging approach. Furthermore, high radiation exposure has been shown to be associated with an estimated lifetime risk for fatal malignancy in operators.

Recently, a novel high-resolution imaging system based on wide band dielectric technology was introduced to guide catheter ablation of atrial arrhythmias. This study presents the first experience applying this novel imaging system with regards to accuracy of visualization of PV-anatomy and PV diameter measurements during CB ablation procedures.

2 | METHODS

2.1 | Study population

Consecutive patients with paroxysmal or early persistent, symptomatic AF undergoing CB-based catheter ablation in conjunction with 3D wide-band dielectric imaging were retrospectively analyzed.

Exclusion criteria were a left atrial diameter > 55 mm, severe valvular heart disease or any contraindication to post-procedural oral anticoagulation.

All patients provided written informed consent. The study was approved by the local ethical board and was performed in accordance to the Declaration of Helsinki.

2.2 | Procedural management

Prior to the procedure, transthoracic and transesophageal echocardiography was performed to rule out intracardiac thrombi and to assess the LA diameter. No additional preprocedural imaging was performed. AF ablation was performed on uninterrupted oral vitamin K-anticoagulation with an INR of 2.0–3.0 on the day of the procedure. In patients treated with novel oral anticoagulants (NOACs), anticoagulation was stopped the day before the procedure.

Catheter ablation was performed under deep sedation using midazolam, fentanyl, and propofol. Vital parameters (pulse, blood pressure, oxygen saturation, and body temperature) were continuously monitored. Heparin boluses were given targeting an activated clotting time > 300 s. A diagnostic catheter was introduced via the right femoral vein and positioned within the coronary sinus. A temperature probe (Circa) was placed within the esophagus at the level of the PVs to monitor esophageal temperatures during freeze cycles. The intraluminal esophageal temperature cut-off was set at 15°C. A single transseptal puncture was performed under fluoroscopic guidance using a modified Brockenbrough technique and an 8.5 F transseptal sheath (SL 0, St. Jude Medical, Inc, St Paul, MN, USA) was introduced into the LA. This was followed by selective PV-angiography in order to identify the individual PV ostia. The transseptal sheath was exchanged over a guidewire for a 15 F steerable sheath (Flexcath advance, Medtronic Inc). A 20 mm circular mapping catheter (Achieve, Medtronic, Inc.) was used in all patients to guide the CB within the LA and to attempt real-time recordings from the targeted PV. Contrast medium injections through the central lumen of the inflated CB were used to verify complete occlusion of the PV-ostium. In all patients, either the second- or the fourth-generation CB was used, and a time-to-effect guided ablation strategy based on PV real-time recordings was performed. After documentation of PVI, the freeze cycle was prolonged for additional 120 s. If no real-time PVI signal recordings could be obtained, a standard freeze cycle of 180 s was applied. No empiric bonus freeze-cycle was applied.

Pericardial effusion after ablation procedures was ruled out in all patients by transthoracic echocardiography. Low molecular-weight heparin was administered in patients on vitamin K-antagonist with an International Normalized Ratio (INR) < 2.0 until a therapeutic INR of 2 to 3 was achieved. Pre-existing therapy with NOACs was reinitiated 6 h after the ablation procedure.

2.3 | Left atrial imaging

The KODEX-EPD system is an open platform that uses any validated EP catheter to create real-time 3D images of the human heart. The KODEX-EPD system takes advantage of the unique dielectric properties of biological tissue by inducing anisotropic electrical fields within the patients’ body and measuring the resultant subtle electrical field differences on the catheter electrodes as they move in the hearts' chambers. The anisotropic fields are induced by external sensors on the body surface and the diagnostic and/or ablation catheter. The system receives and analyzes the electrical field transmission and reflection from all catheter electrodes as they are moved in the cardiac chambers. Structures such as the endocardial atrial surface, cardiac veins, and heart valves cause marked gradients in the electrical field. This “bending of the electrical field” is sensed by the system and used to calculate the geometric characteristics of the 3D image. With this
technique, the KODEX-EPD system collects anatomic information, without immediate physical surface contact, a few millimeters ahead of the catheter electrodes, resulting in a certain degree of "far-field imaging". The catheter serves as an internal distance ruler for scaling of the geometry by comparing the known inter electrode spacing versus the voltage difference between the two electrodes. The system records a specific set of electrical field descriptors for each specific position of the catheter within the cardiac anatomy and can thereby determine relative positions and distances between locations within the chamber. At each location, the electrical field descriptors that the KODEX-EPD system acquires are used to reconstruct the chamber geometry.

Left atrial and PV imaging with the KODEX EPD system was performed using the multipolar Achieve catheter (Medtronic inc.). In all procedures software version 1.4.6 was used. The novel system offers two options for the operator to visualize the cardiac anatomy. First, a 3D surface image provides a more conventional shell of the heart chamber and may be rotated freely. Second, in an innovative approach, the heart may be opened virtually across the 3D surface and this flattened 3D panoramic view ("PANO" view) offers a visualization of the endocardial surface (Figure 1).

2.4 Imaging of PV-anatomy and measurement of PV-dimensions

Selective angiographies of the PVs (right-anterior-oblique (RAO) 30°, left-anterior oblique (LAO) 40°) were performed in all patients, and a 3D anatomy of the PVs using 3D dielectric imaging was also obtained. The dimensions of the PVs as demonstrated by selective angiographies were analyzed and compared to 3D WDIS-based PV imaging.

The maximum, craniocaudal ostial diameters of the ipsilateral right-sided and left-sided PVs and the maximum ostial diameter of the right-sided upper and lower PVs as well as left-sided upper and lower PVs was measured via KODEX-imaging and correlated to fluoroscopic imaging (Figure 2). Fluoroscopic PV-measurements were performed either in RAO 30° (for the right-sided PVs) or LAO 40° (for the left-sided PVs). KODEX-EPD-based PV-measurements were correspondingly carried out in the above mentioned views.

2.5 Endpoints

The primary endpoint was the accuracy of LA and PV anatomy and the correlation of the common ostial diameters of the ipsilateral right-sided and left-sided PVs as well as ostial diameter of the right-sided upper and lower PVs as well as left-sided upper and lower PVs, as demonstrated by selective angiography and EPD-KODEX. Secondary endpoints were defined as acute procedural success and safety. Potential periprocedural complications were defined as pericardial effusion or tamponade, transient ischemic attack (TIA) or stroke as well as hematoma at the access site, any bleeding requiring blood transfusion or interventional treatment as well as esophageal lesions.

2.6 Statistical analysis

Data were collected using Microsoft Excel (Version 15.21.1; 2016). Continuous data are described as mean ± standard deviation (SD), if normally distributed, or as medians (first, third quartile). Categorical data described absolute and relative frequencies.

Passing-Bablok regression analyses were performed to compare PV-measurements of both methods. Furthermore, Bland-Altman plots were used to assess and graphically represent agreement of both methods. Multivariable analyses were performed with R version 3.6.0 (2019).
3 | RESULTS

3.1 | Patient characteristics

A total of 65 patients were analyzed, 42/65 (65%) patients were male, and the mean age was 65 ± 9 years. 29/65 patients (45%) presented with paroxysmal AF, 27/52 patients (53%) suffered from persistent AF.

Detailed patient baseline data are shown in Table 1.

3.2 | Procedural data

Median procedure and fluoroscopy time was 88 [76; 103] and 17 [14; 20] min, respectively. Median cumulative radiation dose was 662 [458; 983] cGycm2. Total LA mapping time was 7 ± 2 min.
### TABLE 1  Patient baseline characteristics

| Variable                      | Statistics       |
|-------------------------------|------------------|
| Gender                        |                 |
| • Male                         | 42 (65%)        |
| • Female                      | 23 (35%)        |
| Age (years)                   | 65 ± 9          |
| Type of AF                    |                 |
| • Paroxysmal                  | 29 (45%)        |
| • Persistent                  | 36 (55%)        |
| LA – diameter (mm)            | 44 ± 9          |
| Ejection fraction (%)         | 52 ± 12         |
| Congestive heart failure      | 20 (31%)        |
| Arterial hypertension         | 50 (77%)        |
| Diabetes mellitus             | 13 (20%)        |
| History of stroke/TIA         | 7 (11%)         |
| CHA2DS2VASc-Score             | 3 ± 1.6         |

Continuous data are summarized as mean ± standard deviations or as medians (25th and 75th percentiles). Categorical data are presented as n (%).

Abbreviations: AF, atrial fibrillation; LA, left atrial; TIA, transient ischemic attack.

### TABLE 2  Procedural and ablation details

| Variable                          | Statistics         |
|-----------------------------------|--------------------|
| Mean minimal temperature (°C)     | −44.5 ± 2          |
| Mean time to PVI, seconds (TTI)   | 42.5 ± 5           |
| Mean temperature at TTI (°C)      | −31 ± 3            |
| Mean total freezing duration (s)  | 163 ± 10           |
| Median total procedure time (min) | 88 [76; 103]       |
| Median total fluoroscopy time (min)| 17 [14; 20]     |
| Cumulative radiation dose (cGycm²)| 662 [458; 983]    |
| Mean total LA-mapping time (min)  | 7 ± 2              |
| Mean total contrast medium (ml)    | 72 ± 28            |

Continuous data are summarized as mean ± standard deviations or as medians (25th and 75th percentiles). Categorical data are presented as n (%).

Abbreviations: PVI, pulmonary vein isolation; TTI, time to isolation; LA, left atrial.

The overall mean freeze cycle duration was 163 ± 10 s and the mean minimal CB temperature was 45 ± 2°C. Mean time to isolation (TTI) was 43 ± 5 s. All PVs could successfully be isolated. Detailed procedural factors are given in Table 2.

### 3.3 Variations in PV-anatomy

A total of 260 PVs in 65 patients were analyzed. A normal PV anatomy, which means two right- and two left-sided PVs with separate ostia, was found in 63/65 (97%) patients. In 1/65 (2%) patients, an additional right-middle PV was suggested via fluoroscopy and could be verified using the novel dielectric imaging system. Furthermore, one right-common PV was only depicted by the KODEX-EPD imaging system, and might have been overlooked when only using fluoroscopic PV-imaging. Figure 3 provides an exemplary presentation of the right-middle PV.

### 3.4 PV diameter measurements

The median ostial diameter of the ipsilateral left- and right-sided PVs was 38 [34; 43] mm and 37 [34; 40] mm when assessed by fluoroscopy and 40 [36; 43] mm and 39 [35; 42] mm when measuring via KODEX-EPD. For the left superior and left inferior PV, a median ostial PV diameter of [17 16; 21] mm and 17 [15; 20] mm was measured fluoroscopically, 19 [17; 23] mm and 18 [15; 21] mm when assessed by the novel imaging system. The median PV diameter of the right superior and inferior PV was 17 [16; 20] mm and 15 [13, 17] mm when depicted via fluoroscopy and 17 [16; 20] mm and 17 [15; 19] mm when measured by KODEX-EPD. There was no statistically significant difference between both methods regarding PV- measurement.

KODEX-EPD overestimated fluoroscopic measurements by 1.08 mm (95% limits of agreement of −1.93 mm and 4.1 mm). Detailed Passing-Bablok and Band-Altman analyses are given in Figure 4 and Figure 5.

### 3.5 Periprocedural complications

In 1/65 (2%) patient, a mild post-interventional pericarditis occurred. The patient recovered without sequelae. No major complications were observed.

### 4 DISCUSSION

This study is the first to evaluate the accuracy of a novel 3D WDIS in conjunction with CB-based ablation procedures with regards to PV-diameter measurements.

The main findings are as follows:

1. Creation of high-resolution images of cardiac structures using the novel KODEX-EPD system was feasible and safe using the multipolar Achieve catheter during CB ablation;
2. the novel WDIS was beneficial with regards to delineating anatomical PV variations during CB ablation
3. the WDIS accurately visualizes PV-anatomy with a high correlation to angiographic assessment.

### 4.1 Feasibility and safety of CB-based PVI in conjunction with a novel WDIS

During our study, 260 PVs were identified and could successfully be isolated. No major complications were observed. The present data
Figure 3 The KODEX-EPD system easily demonstrates a right middle pulmonary vein (RMPV) in this patient, especially using the flattened panoramic view with the PANO view mode (posterior-anterior view, right panel). LSPV = left superior pulmonary vein; LIPV = left inferior pulmonary vein; RSPV = right superior pulmonary vein; RMPV = right middle pulmonary vein; RIPV = right inferior pulmonary vein [Color figure can be viewed at wileyonlinelibrary.com]

Therefore confirm, that CB-based PVI in conjunction with the novel WDIN is feasible and safe with a high rate of acute efficacy. Whereas in principle any diagnostic catheter can be used for LA imaging, it appears reasonable to use the octapolar Achieve circular mapping catheter (Achieve, Medtronic, Inc.) during a CB ablation procedure. The Achieve catheter can be fully visualized with the KODEX-EPD system. Moreover, the novel “PANO view” modality enables the operator to easily navigate the Achieve catheter not only within the LA but also into the PVs and the LAA and also helps to prevent unintentional positioning of the circular catheter into the LV. Therefore, the Achieve catheter can be easily navigated within the LA without having to experience a longer learning curve (Figure 6) and appears to be of similar feasibility for the creation of a LA 3D map in conjunction with the KODEX-EPD system when compared to the reported usability during RF procedures.

4.2 High-resolution imaging of the LA- and PV-anatomy

AF is the most common arrhythmia worldwide and its incidence is rising over time. Catheter ablation of AF has evolved from an investigational procedure to the most effective treatment option, and therefore is recommended as a first-line therapy in symptomatic patients. As the PVs have been shown to be the main trigger source, PVI remains the cornerstone of AF-ablation. Anatomical deviations of PV size and branching are reported in 0.76% to 13% of AF patients and right-sided middle PVs and left-common PV ostia are the most common variations. Furthermore Tsao et al. demonstrated that in their patient cohort, ectopy arising from a RMPV was not infrequently seen, and potentially might initiate AF. Thus, reliable depiction of cardiac anatomy, especially of the LA and PVs, is of major importance for effective trigger elimination.

During our study, several anatomical variations of the PV ostia were observed. Our analyses revealed 258 PVs with a normal anatomical configuration. However, in one patient a right-common PV was documented. Furthermore, in another patient an additional RMPV was observed. Identification and detailed visualization of both of these PV can be improved by use of WDIN and therefore, its use might not just be beneficial for straightforward anatomic findings but particularly for challenging variations.

Despite PV-anatomy and anatomical PV-variations, there are some other LA structures of major importance during LA catheter ablation, not only for optimizing clinical outcomes, but also to avoid
FIGURE 4  Statistical evaluation of PV-diameter measurements showing Passing-Bablok regression plots for demonstration of correlation between fluoroscopy and KODEX-EPD. Solid lines represent regression equation. Broken lines represent regression estimation. Blue field represents 95% confident band. Confidence intervals (CI) for intercept and slope are shown below the Passing-Bablok plots. Both methods (KODEX-EPD and fluoroscopy) are assessed congruent if the intercept is zero and the slope is 1. Thus these values are included in every CI, the hypothesis of congruent methods cannot be rejected. LPV = left pulmonary vein; LSPV = left superior pulmonary vein; LIPV = left inferior pulmonary vein; RPV = right pulmonary vein; RSPV = right superior pulmonary vein; RIPV = right inferior pulmonary vein [Color figure can be viewed at wileyonlinelibrary.com]
periprocedural complications. For example, spiral mapping catheter entrapment in the mitral valve is a known complication during catheter ablation procedures. The worldwide survey by Cappato et al. reported valve damage in approximately 0.07% of all analyzed procedures.\textsuperscript{18} However, this severe complication may be underestimated as a retrospective review reported a significantly higher incidence of catheter entrapment in the mitral valve apparatus causing damage and loss of valve function.\textsuperscript{19} Furthermore, AF ablation in patients post percutaneous mitral valve repair is performed more and more often as the coincidence is rising. In these procedures, catheter interaction with the Mitra-Clip itself may pose another potential risk.\textsuperscript{20} The novel imaging system, in particular with its “PANO view” mode, exactly visualizes important anatomical details, in particular the delineation from the LA to the valves, and therefore might facilitate precise and safe catheter maneuvering throughout the procedure and minimize the risk of periprocedural valve damage.\textsuperscript{21} During our study no entrapment of the Achieve catheter in the mitral valve was identified. Also, unintended insertion of the Achieve catheter and consecutively of the CB into the LAA with potential perforation can effectively be prevented.
4.3 Accurate PV ostial shape and diameter visualization using the novel WDIS

Precise visualization of the PV-anatomy is indispensable during AF- ablation and exact imaging of PV ostia is important for the acute and long-term effectiveness of an ablation procedure.\(^\text{22}\)

(1) Pre-imaging out of date

To date, many centers still routinely perform expensive additional pre-procedural imaging using computed tomography (CT) or cardiac magnetic resonance imaging (MRI) to visualize LA and PV anatomy and to identify PV-variations such as LCPV or to determine ablation strategy and energy. Despite cost-intensiveness, the availability of pre-procedural imaging is still limited in many centers. Furthermore, this means—in terms of CT-imaging—additional radiation exposure for the patient.\(^\text{23}\) The alternative use of a pre-procedural MRI, on the other
FIGURE 6  KODEX-EPD provides CT-like images of the LA and enables real-time Achieve catheter visualization and therefore facilitates catheter navigation within the LA. CT = computed tomography, LA = left atrium [Color figure can be viewed at wileyonlinelibrary.com]

An adequate and precise reconstruction of the PVs and ostial PV diameter is not only essential in terms of efficacy but also with regard to safety. Even if PV-stenosis is a rare complication during CB-based PVI, PV stenosis remains a severe complication resulting in highly symptomatic patients and its treatment is still challenging. Thus, the novel 3D WDIS with its high-resolution imaging and accurate PV-visualization may further help to prevent PV-stenoses not only during CB- but - more importantly - also during RF-based ablation procedures.

4.4 Future perspectives

Our study reports on first experiences with the novel 3D WDIS during CB-based AF-ablation and could confirm procedural feasibility and safety and demonstrate high accuracy of the system regarding assessment of LA structures and PV-dimensions. Based on the findings of this study, which confirm accuracy of the imaging modalities of the KODEX-EPD system, CB-based PVI in conjunction with the recently introduced CB occlusion tool might enable to waive PV angiographies. The KODEX-EPD system therefore may overcome important limitations of CB-based AF-ablation including high radiation exposure and the need of potentially toxic dye in the near future.

In addition, intraprocedural visualization of lesion quality, based on local interrogation of the changes in tissue dielectrics, is under evaluation. Besides, bipolar voltage maps are already fully available and can be used at baseline and post PVI. The implementation of high-density electroanatomical mapping is expected to be available soon. This will offer the opportunity to optimize substrate-based ablation strategies
during the first and also during redo procedures. Therefore, not only RF-based, but also balloon-based AF-ablation – first and foremost CB-based ablation— in combination with the novel imaging system may allow for substrate-based catheter ablation in addition to PVI without the need for additional mapping systems, which may be beneficial especially in patients with persistent and long-standing persistent AF.

4.5 Study limitations

The study findings are based on a retrospective single-center experience. Nonetheless, this is the first study presenting first experiences of KODEX-EPD codex used during CB procedures and second, this is the largest study reporting on the accuracy of assessment of PV-dimensions in comparison to PV angiography during CB ablation.

5 CONCLUSION

The novel 3D WDIS is feasible to create high-resolution images of cardiac structures during CB ablation procedures and accurately visualizes PV-anatomy.

ACKNOWLEDGMENTS

Open access funding enabled and organized by Projekt DEAL.

CONFLICTS OF INTEREST

Metzner received speaker’s honoraria and travel grants from Medtronic, Biosense Webster, Bayer, Boehringer Ingelheim and Cardiofocus. S. A. Rillig received travel grants from Biosense, Medtronic, St. Jude Medical, Cardiofocus, EP Solutions and Ablamap and lecture and consultant fees from St. Jude Medical, Medtronic, Biosense, Cardiofocus, Novartis and Boehringer Ingelheim.

DATA AVAILABILITY STATEMENT

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

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How to cite this article: Rottner L, Nodorp M, Jessica W, et al. High anatomical accuracy of a novel high-resolution wide-band dielectric imaging system in cryoballoon-based ablation. *Pacing Clin Electrophysiol*. 2021;44:1504–1515. https://doi.org/10.1111/pace.14324.