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First data on cardiac mapping and outcome of pulmonary vein isolation using a novel ablation catheter with tip mini electrodes☆

Lena Loehr, Sebastian Lask, Florian Heringhaus, Tanja Lotz, Kaffer Kara, Andreas Mügge, Alexander Wutzler *

Cardiovascular Centre, St. Josef-Hospital, Ruhr-University Bochum, Germany

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ABSTRACT

Aims: Pulmonary vein isolation (PVI) is a standard treatment of atrial fibrillation (AF). AF recurrence after PVI occurs in a substantial number of cases. A novel ablation catheter equipped with mini-electrodes (ME) may facilitate PVI. Our study evaluated outcome after PVI with the ME catheter compared to a standard catheter.
Methods: Patients undergoing PVI with the ME catheter were compared to a control group ablated with a standard contact force sensing catheter. Freedom of AF after 12 months was the study endpoint. Additionally, low voltage areas (LVA) <0.5 mV were identified with a circular mapping catheter (CMC) and the ablation catheter in each group. LVA were compared between the maps obtained with the CMC and the ME or standard catheter, respectively.
Results: A total of 110 patients underwent PVI with ME catheter (n = 59) or the standard catheter (n = 51). Procedure duration (117.4 ± 43 vs. 103.1 ± 32.8 min, $p = 0.15$), radiation dose (1135.6 ± 1125.7 vs. 1078.8 ± 951.4 μGy/m^2, $p = 0.91$), incidence of complications and 12-month success rate (64.4 vs 72.5%, $p = 0.36$) were not significantly different between the groups. LVA were significantly smaller when obtained with the standard catheter compared to the CMC (14 ± 13 vs. 58.5 ± 22.1 cm^2, $p < 0.001$), while no such difference was seen for mapping with the ME compared to the CMC (37 ± 30.3 vs. 33.4 ± 39 cm^2, $p = 0.4$).
Conclusion: Clinical outcomes are comparable between ME catheter and a standard contact force sensing catheter. Furthermore, better LVA detection points to improved mapping capabilities of the ME catheter.

1. Introduction

Circumferential pulmonary vein isolation (PVI) has become a standard treatment for symptomatic atrial fibrillation (AF) [1]. The basic principle of PVI is the creation of an electrical conduction block around the pulmonary veins (PV) [2,3]. However, reconnection over the ablation line and recurrence of AF after PVI are not uncommon [1,3]. Recently, a novel ablation catheter equipped with three additional mini electrodes (ME) on the catheter tip was introduced [4–6]. Cardiac mapping and monitoring of lesion maturation are facilitated with the use of the ME in AF procedures, because of reduction of far-field recordings and improved localization of electrograms [5,6]. However, up to today no data exist on mapping and AF ablation with the novel ME catheter compared to a standard approach. The aim of our study was to compare procedural parameters and outcome of PVI after ablation with the ME catheter compared to ablation with a standard contact force-sensing catheter.

2. Methods

2.1. Patients

Consecutive patients that underwent circumferential PVI using RF energy as a first procedure for the treatment of AF were retrospectively included from November 2015 to April 2017. From May 2016 to April 2017, catheter ablation was performed with the ME catheter (ME group). Patients, who were ablated with a standard contact force sensing catheter from November 2015 to May 2016 by the same operators served as historical control group. Patients with concomitant arrhythmias, patients in whom additional lesions were applied, patients in whom cryoablation was used or patients without complete follow-up were excluded from the study. The study complied with the declaration of Helsinki.

2.2. Ablation procedures

All patients underwent wide antral circumferential PVI. Procedures were performed in a fasting state and left atrial thrombus was ruled out with transesophageal echocardiography. All patients underwent electrophysiological investigation under intravenous sedation with midazolam and propofol during continuous monitoring of blood pressure and oxygen saturation.

After bilateral femoral venous access, a decapolar catheter was placed in the coronary sinus and trans-septal puncture was performed with the use of a steerable sheath (Agilis, St. Jude Medical, Saint Paul, MN, USA) and a fixed curved sheath (SL0, St. Jude Medical) and a Brockenbrough needle (BRK Transseptal Needle, St. Jude Medical). A 10-pole circular mapping catheter (Inquiry Optima, St. Jude Medical) was introduced via the fixed curved long sheath. An open-irrigated ablation catheter was introduced via the steerable sheath.

☆ The authors report no relationships that could be construed as a conflict of interest.

* Corresponding author at: Cardiovascular Centre, St. Josef-Hospital, Ruhr-University Bochum, Gudrunstraße 56, 44791 Bochum, Germany.
E-mail address: Alexander.Wutzler@ruhr-uni-bochum.de (A. Wutzler).

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In the ME group an Intella Tip Micro Fidelity MiFi O/I (Boston Scientific, Boston, MA, USA) was used, while in the control group a TactiCath Quartz (St. Jude Medical) was used. In the ME catheter, MEs are radially distributed around the catheter tip with 1.2 mm inter-electrode spacing, each ME with a surface area of 0.8 mm (Fig. 1) [6]. The MEs are embedded in a standard 4.5 mm tip [6]. The catheter used in the control group is a contact force sensing catheter with a 3.5 mm tip and an inter-electrode spacing of 2-5-2. The circular mapping catheter was positioned in the PV ostia for mapping connection and confirmation of electrical PV disconnection after ablation. Circumferential pulmonary vein isolation was performed with the use of a 3D-Mapping-System (Ensite Velocity, St. Jude Medical) and an Ampere RF ablation generator (St. Jude Medical). Temperature was set at a maximum of 43 °C, maximum power was set at 35 W (25 W at the posterior wall). The procedural endpoint was defined as complete isolation of the pulmonary veins and was confirmed by bi-directional block with the circular and the ablation catheter. Adenosine was administered to screen for dormant PV conduction after PV disconnection in patients without contraindications (asthma, severe coronary artery disease). Heparin was continuously administered intravenously. An activated clotting time of >300 s was targeted throughout the procedure. All patients gave written informed consent.

2.3. Left atrial voltage mapping

In a subset of patients with significant low voltage areas (>5%), cardiac mapping was performed with the CMC and additionally with the use of the ME catheter or the standard catheter respectively. A complete three-dimensional reconstruction and a bipolar voltage map of the LA, LAA and PVs were created during sinus rhythm with all 10 electrodes of the CMC catheter, a model filling threshold ≤10 mm, and a mapping interpolation set at 10 mm as described before [7]. Then, a second voltage map was created using the mini electrodes of the ME catheter (ME group) or the distal electrodes of the ablation catheter (control group).

All bipolar voltage maps were analyzed as previously described using the field scaling function of the EnSite system [7]. Voltage was determined as the amplitude of the local bipolar signal using an automated algorithm. Voltage measurement was manually modified if necessary. Areas with voltage values <0.5 mV were considered as left atrial low voltage areas (LVA) [7]. The size of LVA (cm^2) was determined using the marker measurement tool [7]. The size of LVA was compared in each group between the CMC and the ME catheter and the CMC and the standard catheter, respectively.

2.4. Follow-up

Patients were followed up for 12 months. Follow-up visits including 12-lead and 7-day Holter ECG were scheduled 12 months after discharge and if patient presented with symptoms suggestive for AF. Episodes of AF/atrial arrhythmias longer than 30 s that occurred within 12 months after ablation with a blanking period of the first 3 months after ablation were considered to indicate a recurrence of AF.

2.5. Statistical analysis

Data are presented as absolute numbers and percentages for categorical variables or mean ± standard deviation (SD) for continuous variables. Chi square test was used to compare discrete variables, Mann Whitney *U* test was used to compare continuous variables. All analyses were performed using SPSS software version 24.0 (SPSS Inc., Chicago, IL, USA). A *p* value of <0.05 was considered statistically significant.

3. Results

A total of 110 patients underwent PVI with ME catheter (n = 59) or the standard catheter (n = 51). Patients' characteristics are depicted in Table 1. No significant differences were observed regarding comorbidities, age, sex, medication or left ventricular function, LA diameter or percentage of LVA in LA. (See Fig. 2.)

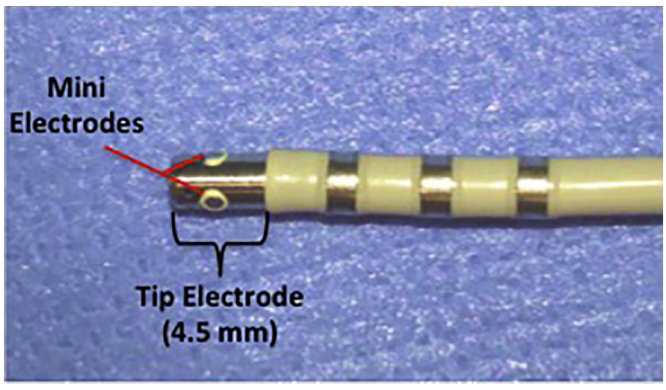

Fig. 1. Ablation catheter equipped with mini electrodes.

Table 1
Baseline characteristics of study patients and controls. ACEI = angiotensin converting enzyme inhibitor, AF = atrial fibrillation, ARB = angiotensin receptor blocker, BMI = body mass index, CAD = coronary artery disease, COPD = chronic obstructive pulmonary disease, DOAC = direct oral anticoagulant, LA = left atrium, LVA = low voltage area (<0.5 mV), LVEF = left ventricular ejection fraction.

Patient characteristics	ME catheter (n = 59)	Control (n = 51)	*P*
Characteristics			
Age (years) (SD)	65.9 (10.2)	66 (10.1)	0.96
Male (%)	34 (57.6)	24 (47.1)	0.27
BMI (SD)	30 (9.5)	29.6 (5.1)	0.54
Hypertension (%)	45 (76.3)	36 (70.6)	0.5
CAD (%)	13 (22)	14 (27.5)	0.51
Diabetes mellitus (%)	2 (3.4)	6 (11.8)	0.09
COPD (%)	5 (8.5)	3 (5.9)	0.6
LVEF (%) (SD)	55.2 (6.8)	55.7 (8.7)	0.19
LA diameter (mm) (SD)	41.8 (5.7)	39.9 (5.6)	0.11
Percentage of LVA in LA (SD)	8 (11.1)	6.3 (8.6)	0.47
Paroxysmal AF (%)	28 (47.5)	26 (51)	0.87
Medication			
Beta receptor blocker (%)	49 (83.1)	44 (86.3)	0.64
ACEI (%)	22 (37.3)	17 (33.3)	0.67
ARB (%)	14 (23.7)	16 (31.4)	0.37
Statin (%)	21 (35.6)	16 (31.4)	0.64
Aspirin (%)	7 (11.9)	5 (9.8)	0.73
Clopidogrel (%)	2 (3.4)	1 (1.9)	0.65
Vitamin K antagonist (%)	20 (33.9)	16 (31.4)	0.78
DOAC (%)	36 (61)	33 (64.7)	0.69
Antiarrhythmic agent (%)	7 (11.9)	3 (5.9)	0.28

3.1. Procedural endpoints and outcome

Complete PVI as acute procedural endpoint was achieved in all cases (Table 2). LA procedure duration (117.4 ± 43 vs. 103.1 ± 32.8 min, $p = 0.15$), radiation dose (1135.6 ± 1125.7 vs. 1078.8 ± 951.4 μGy/m^2, $p = 0.91$), incidence of complications and 12-month success rate (64.4 vs 72.5%, $p = 0.36$) were not significantly different between the groups. Duration of RF applications was significantly shorter in the ME group (74.1 ± 18.8 vs. 86.5 ± 21.7 s, $p = 0.01$).

3.2. Left atrial voltage mapping

Extent of left atrial low voltage areas was obtained with the circular mapping catheter and the ablation catheter in each study group in a sub-study (n = 9 in each group). Extent on LVA determined with the CMC was not significantly different between ME group and control group (33.4 ± 39 vs. 58.5 ± 22.1 cm^2, $p = 0.1$).

After additional mapping with the ablation catheter, extent of LVA did not differ significantly between maps obtained with the ME catheter compared to the CMC (37 ± 30.3 vs. 33.4 ± 39 cm^2, $p = 0.4$) in the ME group. In contrary, in the control group LVA were significantly smaller when obtained with the standard ablation catheter compared to the CMC (14 ± 13 vs. 58.5 ± 22.1 cm^2, $p < 0.001$).

4. Discussion

We here present first data on cardiac mapping and outcome of pulmonary vein isolation using a novel ablation catheter equipped with additional ME on the catheter tip. The main results of our study are:

1. Acute success, procedural feasibility and outcomes 12 months post-ablation were not significantly different between PVI with the ME catheter compared to a standard contact force-sensing catheter.
2. The extent of LVA was significantly smaller when obtained with a standard contact force-sensing catheter compared to a CMC, while

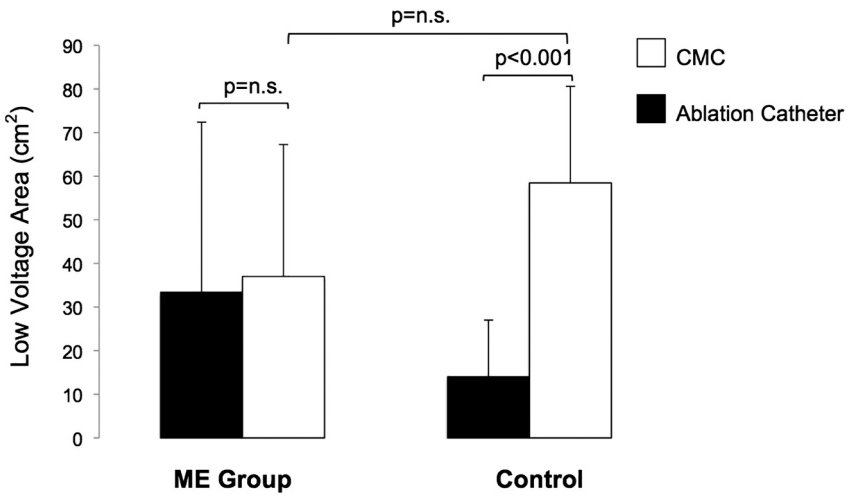

Fig. 2. Results of the low voltage mapping: Extent of left atrial low voltage areas (LVA) obtained with the circular mapping catheter and the ablation catheter in each study group (sub-study with n = 9 in each group). In the ME group, extent of LVA did not differ significantly between maps obtained with the ME catheter compared to the CMC (37 ± 30.3 vs. 33.4 ± 39 cm^2, $p = 0.4$). In the control group, LVA were significantly smaller when obtained with the standard contact force-sensing catheter compared to the CMC (14 ± 13 vs. 58.5 ± 22.1 cm^2, $p < 0.001$). Extent on LVA was not significantly different between ME group and control group (33.4 ± 39 vs. 58.5 ± 22.1 cm^2, $p = 0.1$).

the extent of LVA obtained with the ME was not significantly different from LVA obtained with the CMC.

4.1. Procedural endpoints and outcome

Previous publications on intraprocedural data of ME catheters in electrophysiological procedures in humans and animal models have shown improved monitoring of lesion formation and improved detection of PV potentials compared to standard bipolar electrodes [5,6,8,9]. The results of our study generally confirm the previous findings and show that procedure duration or radiation dose is not increased with the use of the novel catheter. Furthermore, our results show for the first time that acute and 12-month outcome are comparable to a standard catheter with contact force sensing. Additionally, mean duration of RF pulses was significantly shorter in the ME group in our study, which may be explained by the improved lesion maturation capabilities of the catheter. Noteworthy, the standard catheter used in our study was a contact force-sensing catheter. The results of PVI with contact force-sensing catheters are generally better compared to PVI performed without contact force sensing even in smaller studies [10,11]. Although we cannot conclude from our data that the use of ME is equal to the use of contact force sensing, our results are encouraging and show a general feasibility of the ME catheter.

Table 2
Procedural data and outcome of study patients and controls. DC = dormant conduction, LA = left atrial, PV = pulmonary vein, RF = radiofrequency.

	ME catheter (n = 59)	Control (n = 51)	*P*
Procedural data			
Complete PV isolation (%)	59 (100)	51 (100)	–
Total LA procedure time (min) (SD)	117.4 (43)	103.1 (32.8)	0.15
RF ablation time (min) (SD)	30.8 (10.2)	29.5 (6.2)	0.99
Duration of RF applications (s) (SD)	74.1 (18.8)	86.5 (21.7)	0.01*
Dose area product (μGy/m^2) (SD)	1135.6 (1125.7)	1078.8 (951.4)	0.91
Patients with DC after adenosine (%)[a]	8 (19)	5 (9.8)	0.42
Complications			
Pericardial effusion (%)	1 (1.7)	0 (0)	0.35
Stroke/TIA (%)	0 (0)	1 (2)	0.28
Vascular complication (%)	5 (8.5)	4 (7.8)	0.9
Charring (%)	0	0	–
Steam pop (%)	0	0	–
Follow-up			
12-month success rate (%)	38 (64.4)	37 (72.5)	0.36
Left atrial tachycardia after PVI (%)	0 (0)	1 (2)	0.28

[a] Available for n = 42 in the ME group and n = 40 in the control group.
* Statistically significant.

4.2. Left atrial voltage mapping

An interesting finding of our study is that LVA obtained with the standard catheter were significantly smaller compared to the CMC, while this was not observed for the ME catheter. Several previous studies investigated the mapping characteristics of multi-electrode catheters versus ablation catheters and the effect of electrode size and electrode spacing on the detection on LVA. Stinnett-Donnelly et al. postulated based on a computational model that smaller electrodes and closer electrode spacing increase special resolution of cardiac mapping [12]. Accordingly, a study by Anter et al. found an increased mapping resolution especially in LVA with 1-mm electrode catheters compared to 4-mm electrode catheters [13]. A study from our research group also revealed a mismatch of LVA areas obtained with a 1-mm CMC and a 4-mm ablation catheter [7]. Therefore, the difference in LVA size between contact force catheter-mapping and CMC-mapping in our study is most likely a consequence of the lager electrode of the contact force catheter (3.5 mm). The fact that LVA size determined with CMC and ME catheter is similar can be explained by the similar electrode size (CMC 1-mm, ME 0.8-mm).

Yet, mapping and ablation of arrhythmogenic left atrial substrate, especially LVA, are becoming increasingly important in AF ablation [14,15]. Thorough LVA mapping is crucial to localize non-PV ablation targets and optimal special resolution of ablation catheter electrograms during ablation is desirable. The use of the ME catheter may facilitate identification of LA substrate during ablation.

4.3. Limitations

Our study has several limitations that have to be acknowledged. The study was a non-randomized retrospective single-center study and the sample size was small. Especially in the LVA mapping sub-study, the sample size was limited and the difference in mean absolute values and the standard variation are relatively high. Furthermore, the follow-up was only based on one 7-day Holter after 12 months. Nonetheless, this is the first study on PVI outcomes with this novel catheter and also the largest trial that was performed with ME catheters so far. Our study should be considered as first clinical trial with this novel device in PVI and should be confirmed in a prospective randomized study.

5. Conclusions

Clinical outcomes of PVI are comparable between ME catheter and a standard contact force sensing catheter. Furthermore, shorter duration of single RF applications and better LVA detection point to improved mapping capabilities of the ME catheter.

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