

Treatment of Patients after Pulmonary Vein Isolation in Persistent Atrial Fibrillation - Combined Use of a High-Density Map and Robotic Navigation

Yuriy Bychkov ^{1*}, Zdravena Doneva ¹, Björn Buchter ¹, Margarita Kreuzer ², P. Christian Schulze ³, Burkhard Hügl ¹

¹Medicine Doktor, Marienhaus Clinic St. Elisabeth Neuwied, Germany.

²Epidemiology, Employee Stereotaxis, Germany.

³Medicine Doctor, Professor, Universitätsklinikum Jena, Germany.

*Corresponding Author: Yuriy Bychkov, Medicine Doktor, Marienhaus Clinic St. Elisabeth Neuwied, Germany.

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Abstract

Objectives and Background: Atrial fibrillation (AF) is still associated with higher recurrence rate. This is prospective study of Redo pulmonary vein isolation (PVI) combined with remote magnet navigation. We have done high density mapping and in retrospective Analysis we tried to find criteria for better Ablation success.

Materials and Methods: 50 patients (male 36, female 14) with indication for Redo-PVI were included. A 20 polig multi-electrode catheter was used for mapping. Mapping data were collected before and after ablation and processed in terms of low-voltage areas bipolar (3 groups: 0.05-0.15 mV, 0.15-0.25 mV, 0.25-0.5 mV) and change in unipolar amplitude at the ablation lesions. The primary endpoint (symptom freedom at 12 months) was evidenced by follow-up examinations at 3, 6, 9, 12 months. Non-parametric statistical methods were used for variables with non-normal distributions. Trends in success rates were evaluated using the Kaplan-Meier methodology and compared using a log-rank test.

Results: In all analysed low-voltage bipolar groups occurs a change in the distribution after ablation in patients with AF. There are 3 parameters which related with endpoint: area of bipolar signals 0.05-0.15 mV (Me +32%, [95% CI: -10% to +167%], $p < 0.001$), the unipolar amplitude at the applied ablation lesions (Me -0.45 mV [95% CI: -0.15 to -1], $p < 0.001$) and unipolar amplitude at the attached ablation lesions (lower amplitude was with recurrence associated, $p = 0.004$). According to ROC analysis and logistic regression: failure to meet all 3 criteria accompanied with a 67% probability of symptomatic recurrence, if all 3 criteria are met, it is expected to have an approximately 81% success rate within the 12 months.

Conclusion: Analysis of high-density map including 3 criteria, help us to improve ablation success.

Key-words: high-density mapping; unipolar; bipolar; stereotaxis; pentaray

Introduction

Atrial fibrillation (AF) is an important clinical problem because affected patients suffer from decreased performance, dyspnea, palpitations, which accordingly lower the quality of life while increasing the mortality rate.[1,2]

A trigger (e.g., atrial extrasystoles, in most patients from arrhythmogenic myocardium in and around the pulmonary veins) and a substrate (fibrosis and remodeling of the atria) are necessary for the development of AF. [3,4] Several therapeutic approaches to atrial fibrillation exist. [5] These include the maintenance of normal ventricular frequency (frequency

control) and the maintenance of sinus rhythm (rhythm control). The two strategies can be approached with drugs and/or interventions. [6,5]

Despite the emergence of different ablation methods, the recurrence rate remains relatively high in AF and according to various reports is 25-80% after single ablation and 10-50% after multiple ablations in patients with persistent AF. [7,8,9]

Radiofrequency ablation is the most used intervention for cardiac arrhythmias, but safe manipulation of the catheter in heart cavities is not easy and is associated with risks. Real-time visualization of the position used to be possible only with irradiation throughout the procedure [10]. The robotic magnetic navigation (RMN) system for catheter ablation offers the advantages of precise and flexible catheter navigation [11,12].

The goal of this prospective study is to improve the ablation of AF, by extensively analyzing high-resolution maps to gain more electrophysiological data about the state of the atrium and adapt the ablation strategy accordingly. [13] The use of a robotic magnetic navigation system was chosen to facilitate the precise execution of the chosen strategy and to maximize procedural safety as well as reliability due to the higher stability of the catheter. [14,15]

Scientific data regarding bipolar [16,17,18] and especially unipolar [19,20] mapping for AF ablation is limited. This is likely associated with high rates of arrhythmia recurrence. [21]

Therefore, this study aims to more accurately assess mapping data in AF ablation, analyze the importance of electrode spacing in creating high-density maps, search for new clinically relevant characteristics related to bipolar mapping in the 0.05-0.5mV signal amplitude range, assess the importance of unipolar mapping in AF ablation, and identify possible prognostic predictors related to the probability of recurrence.

Materials and Methods

Settings and participants

The results presented below are from an analysis of 50 patients treated at St. Elisabeth Hospital Neuwied for repeat ablation therapy of persistent AF after recurrence. Data collection and follow-up examinations were performed after the written informed consent of the patients and prior review of the study protocol by the ethical committee of the Marienhaus Clinic St. Elisabeth Neuwied. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

A total of 50 patients participated in the study from 2017 to 2020. These patients had received pulmonary vein isolation (PVI) in the past and had a clinically relevant, symptomatic, drug-refractory recurrence. After the

patient's consultation, the decision was therefore made to repeat PVI as a treatment strategy. AF was classified as persistent in all patients. [5,9]

Variables and assessment

All patients underwent computed tomography (CT) of the heart before ablation. Furthermore, transesophageal as well as transthoracic echocardiography with the recording of hemodynamic as well as morphological parameters (LV ejection fraction, LA dimensions as well as LAA flow, valvular vitiation) was performed in all patients after a detailed work-up. Electrophysiology studies (EPS) were performed under deep sedation and heparin as an anticoagulant (ACT (activated clotting time) target of 300 seconds). [9] The robotic magnetic navigation system Niobe® was used as a catheter control system. The right vena femoralis was used for venous access. Transseptal puncture and placement of SL1 sheath, RA-CS catheter, and His bundle catheter were performed.

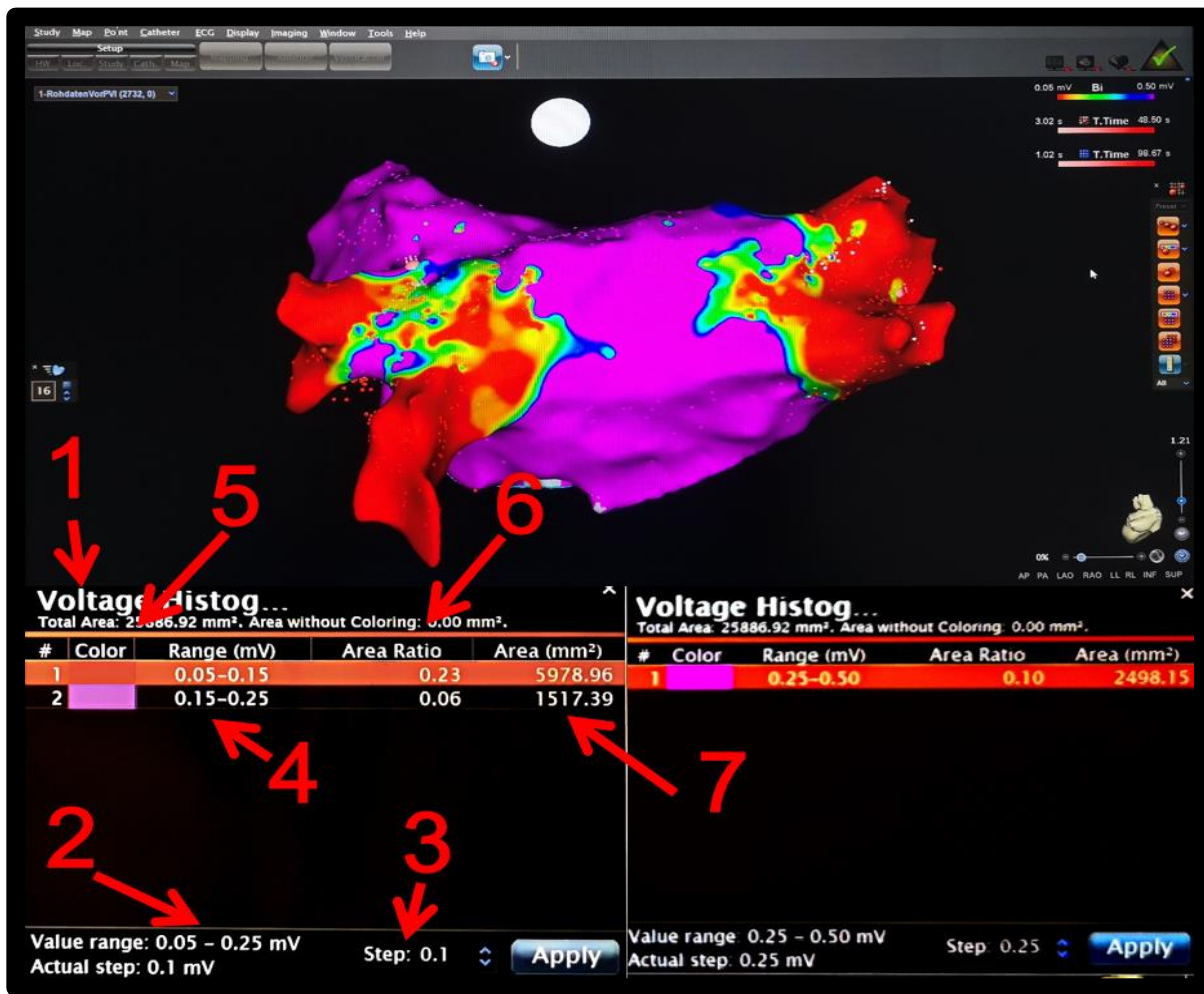
The 5-arm 20-polig high-density mapping CARTO® Pentaray catheter was used as the examination catheter for the preparation of electrophysiological maps of the left atrium in all patients. Half of the examinations were performed with a mapping catheter with 4-4-4 mm sensor spacing on each of the 5 arms, and the second half of the cases were performed with a catheter with 2-6-2 mm spacing.

Data collected with CT were fused with electrophysiological data. After the creation of the map, ablation was performed using the robotic magnetic navigation system. The ThermoCool RMT 4-mm EPS catheter was used as the ablation catheter. Ablation was performed by radiofrequency current method, for each ablation lesion 35W, 30 sec, cooling flow 30 ml/min.

All atrial maps were collected in a sinus rhythm. Electrophysiological data were processed using CARTO® 3 software. All bipolar maps were filtered between 30 and 500 Hz. The applied settings were: "Confidense" filter setting, position 10, density 1mm, mapping criteria wavefront. The low-voltage zone was defined as 0.25 to 0.5 mV bipolar. All maps were also tested with limits 0.05 to 0.5 mV bipolar.

The maps were analyzed peri-intervention for low-voltage zones as well as reconnections of the pulmonary veins to devise an appropriate ablation strategy (re-isolation of the pulmonary veins, mitral isthmus line or roofline, etc.). [9] After the ablation procedure, the electrophysiological data were again collected using the CARTO® Pentaray catheter. In this way, differences in signals before and after ablation could be studied.

Using the program extension "Voltage Histogram", a measurement of the areas of the voltage zones selected for the setting and their distribution in the left atrium before and after ablation was performed (**Example shown in figure 1**).



* Due to programming limitations, it was not possible to determine a variable interval (3) in set amplitude limits (2), so for respective maps analysis was done in 2 stages (0.05-0.25 mV bipolar with an interval 0.1 mV as well as 0.25-0.5 mV bipolar with an interval 0.25 mV).

Figure 1: Example of an area measurement corresponding to the various voltage zones in the left atrium. 1 - Program extension "Voltage Histogram". 2 - Set amplitude limit where analysis is necessary. 3 - Set interval. 4 - Calculated amplitude intervals based on the set interval (3) and selected amplitude limit (2). 5 - Color marking of the calculated amplitude intervals (*). 6 - Calculated area of amplitude intervals in relation to the total measured LA area. 7 - Calculated area of amplitude intervals in mm².

To visualize the changes in low-voltage areas before and after ablation and to perform further analysis of specific signal groups, the bipolar low-voltage areas were experimentally divided into 3 areas (0.05mV - 0.15mV, 0.15mV - 0.25mV, and 0.25mV - 0.5mV) and processed for the respective map before and after ablation.

The change in the total amplitude of unipolar signals at the site where the ablation lesion was placed was calculated before and after RF delivery. Analysis of unipolar mapping was performed based on visual detection of amplitude change (measurement limits 0.5-2.0 mV, interval 0.1 mV) at the ablation lesions, which were marked accordingly by the CARTO® 3 program on LA maps (Example shown in figure 2).

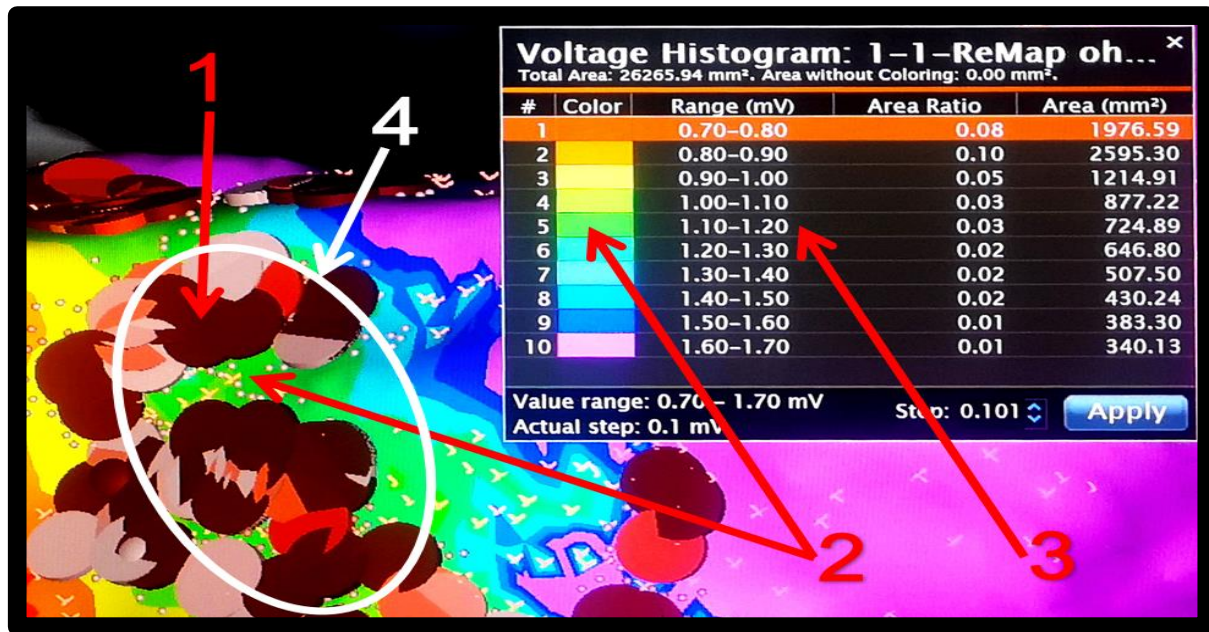


Figure 2: An example of the distribution and the corresponding colored marking of the amplitude of unipolar mapping. 1 - Labeled ablation lesion (spatially localized identically on "pre-ablation as well as post-ablation map"). 2 - Color labeling with corresponding signal amplitude (3).

For this purpose, the zones around pulmonary veins were divided into 2 segments each - above as well as below the respective pulmonary vein (8 in total). If the ablation occurred at deviating locations (e.g., roofline, mitral isthmus line, etc.), the corresponding zones were also analyzed. Then, determination of the mean amplitude of unipolar signals at ablation points was performed based on the colored marking of the corresponding amplitude intervals before as well as after ablation. The marked ablation lesions were without spatial displacement both before and after ablation thanks to an equally used pre-and post-ablation fast anatomical map (FAM).

Statistical Analysis

Normality was assessed by the Kolmogorov-Smirnov test, or when appropriate, Shapiro-Wilk test. Median and interquartile range (IQR) were computed for continuous variables with non-normal distribution. Descriptive statistics for categorical data were expressed in absolute numbers and percentages. For variables with non-normal distributions, the Mann-Whitney U test was used. For comparing frequencies, the Chi-square test was used. Trends in success rates were evaluated using the

Kaplan-Meier methodology and compared using a log-ranking test. A 2-sided P-value of <0.05 was considered significant. All collected data were analyzed using SPSS Statistics 22.0.

Results

As shown in **table 1** a total of N=50 (male=36; female=14) patients participated in the study from 2017 to 2020 with a mean age of 64 years [95% CI (Confidence interval): 46-79]. 48 patients had established antiarrhythmic therapy (12 amiodarone, 17 dronedarone, 18 flecainide, and 1 propafenone). 42 patients discontinued antiarrhythmic therapy 6 months after ablation (symptom-free, sinus rhythmus). 16 patients had coronary artery disease (CAD), 9 patients cardiomyopathy, 12 reduced LV pump function left ventricular ejection fraction (LVEF) (5: LVEF 45-54%, 7: LVEF 30-44%), 30 patients arterial hypertension, and 5 diabetes mellitus. A total of 14 patients had a history of impaired thyroid function with appropriate therapy (euthyroid at the time of the study). Twenty patients had a history of other cardiac arrhythmias (isthmus-dependent atrial flutter 18, AVNRT and isthmus-dependent atrial flutter 1, left atrial tachycardia 2).

	Patients N (%)
	50 (100%)
Male	36 (72%)
Female	14 (28%)
Age (median), years	
Total	64 (95% CI 46-79)
Male	60 (95% CI 46-79)
Female	64 (95% CI 55-74)

BMI (median), kg/m ²	29.5 (95% CI 23-36.3)
Form of disease:	
Persistent	50 (100%)
Antiarrhythmic Therapy:	
Amiodarone	12 (24%)
Dronaderone	17 (34%)
Flecainide	18 (36%)
Propafenone	1 (2%)
Other arrhythmias:	
Isthmus-dependent atrial flutter	18 (36%)
AVNRT	1 (2%)
Left atrial tachycardia	2 (4%)
Total*	20 (40%)
Underlying cardiac disease:	
Coronary artery disease	16 (32%)
Cardiomyopathy	9 (18%)
Other comorbidities:	
Arterial hypertension	30 (60%)
Diabetes mellitus	5 (10%)
Hypothyroidism**	11 (22%)
Hyperthyroidism***	3 (6%)
LV ejection fraction (%):	
normal (>55%)	38 (76%)
slightly reduced (45-54%)	5 (10%)
moderately reduced (30-44%)	7 (14%)

Table 1: Clinical characteristics, comorbidities and antiarrhythmic therapy

The primary endpoint was freedom from symptoms 12 months after AF ablation. This was evidenced by follow-up examinations at 3,6,9,12 months after ablation by interview, clinical examination, and an ECG recording for 7 days. A total of 15 of 50 patients (30%) experienced AF recurrence within the first 3 months after ablation. Cumulatively, 30 of 50

(60%) patients remained symptom-free at 1 year, and 22 of 50 (44%) patients were free of AF.

In this analysis, it was shown that in patients with AF, there is a difference in the distribution of diverse bipolar low-voltage groups after ablation (**Example shown in figure 3**).

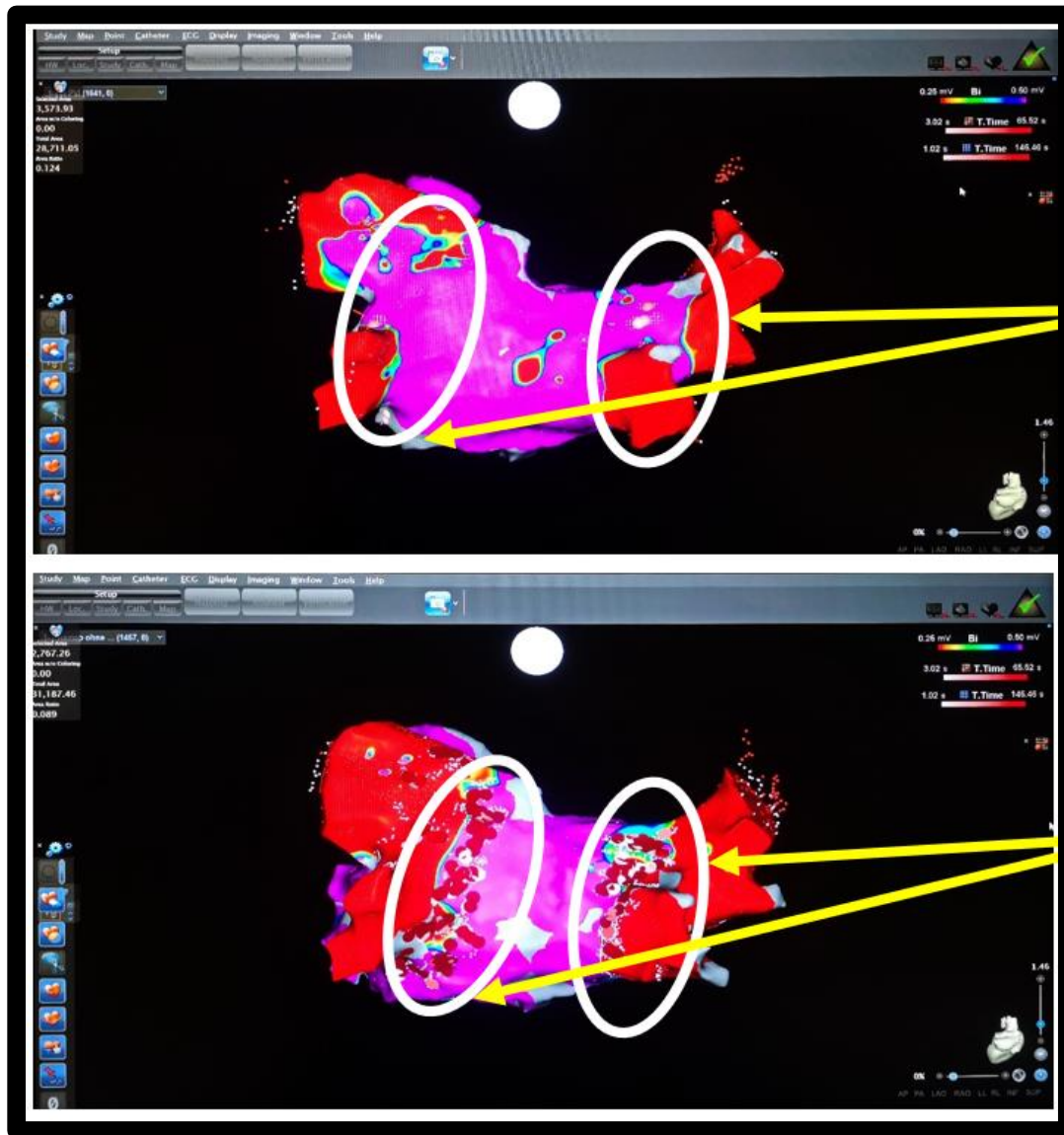


Figure 3: Example of changes in the distribution of voltage zones before (upper picture) and after ablation (lower picture) for a bipolar mapping (measurement limits 0.25-0.5 mV).

Of particular interest as shown in **table 2** was the increase in area of bipolar signals with an amplitude of 0.05-0.15 mV (+32%, [95% CI: -10% to +167%], p<0.001) and the decrease in unipolar amplitude at placed ablation lesions (-39%, [95% CI: -15% to -76%], p<0.001).

Voltage-Zone	median (%)	95% CI	p - value*
Bipolar 0.05-0.15 mV	32	[-10, 167]	<0,001
Bipolar 0.15-0.25 mV	6	[-39, 101]	0,001
Bipolar 0.25-0.5 mV	-8	[-52, 70]	0,03
Unipolar (%)	-39	[-15, -76]	<0,001
Unipolar (mV)	-0.45	[-0.15, -1]	<0,001

*p-value alpha ≤ 0.05 by Wilcoxon-Test

Table 2: Increase and decrease in areas in all studied patients

The two predictors correlate with each other (r Spearman -0.38; p=0.01) and with ablation success in terms of follow-up examinations within the first 12 months after ablation (increase in area of bipolar signals 0.05-0.15

mV, r Spearman -0.29; p=0.04, decrease in unipolar amplitude r Spearman 0.28; p=0.05). Other voltage groups no difference.

Voltage-Zone (mV, %)	symptomatic recurrence		symptom-free		p - value*
	median (%)	95% CI	median (%)	95% CI	
Bipolar 0.05-0.15	21	[-8, +156]	52	[-10, +167]	0.04
Bipolar 0.15-0.25	4	[-31, +101]	12	[-39, +59]	0.21
Bipolar 0.25-0.5	-2	[-45, +44]	-16	[-52 +70]	0.07
Unipolar (%)	-38	[-15, -57]	-39	[-17, -76]	0.59
	median (mV)		median (mV)		
Unipolar (mV)	-0.35	[-0.75, -0.15]	-0.5	[-1.15, -0.1]	0.05
Unipolar (mV) amplitude at the ablation sites	1,1	[0,6 - 2,3]	1,4	[0,6 - 1,8]	0,004

* p-value alpha ≤ 0.05 by Mann-Whitney U test

Table 3: Increase and decrease in areas in patients with symptomatic recurrence within the first 12 months after ablation and symptom-free patients

As shown in **table 3** a difference is observed in the change of the amplitude of the bipolar signals of the lowest voltage group (0.05-0.15 mV). However, if the unipolar signals are not considered in their relativity, but as an absolute change, the data already provides other distribution, which is different from the one given above.

No association was found between atrial enlargement or the presence of CAD (coronary artery disease) as an underlying disease and outcome (freedom from symptoms at 12 months after AF ablation). This proves that already structurally altered atria can be treated with a corrective ablation strategy and a comparable prognosis can be expected.

With the considerable variability of the investigated parameters and a limited patient group, it can be assumed that not all existing correlations could be detected statistically. Even for parameters already found, a boundary determination in the sense of "false-true" was difficult due to a large overlap of the distributions. Nevertheless, utilizing ROC analysis a cut-off limit for the increase of bipolar signals 0.05-0.15 mV, decrease of unipolar amplitude as well as mean unipolar amplitude at the locations selected for ablation could be calculated (sensitivity and specificity corresponding to 67% and 70%, 67% and 55%, 70% and 73%) (**Figure 4**).

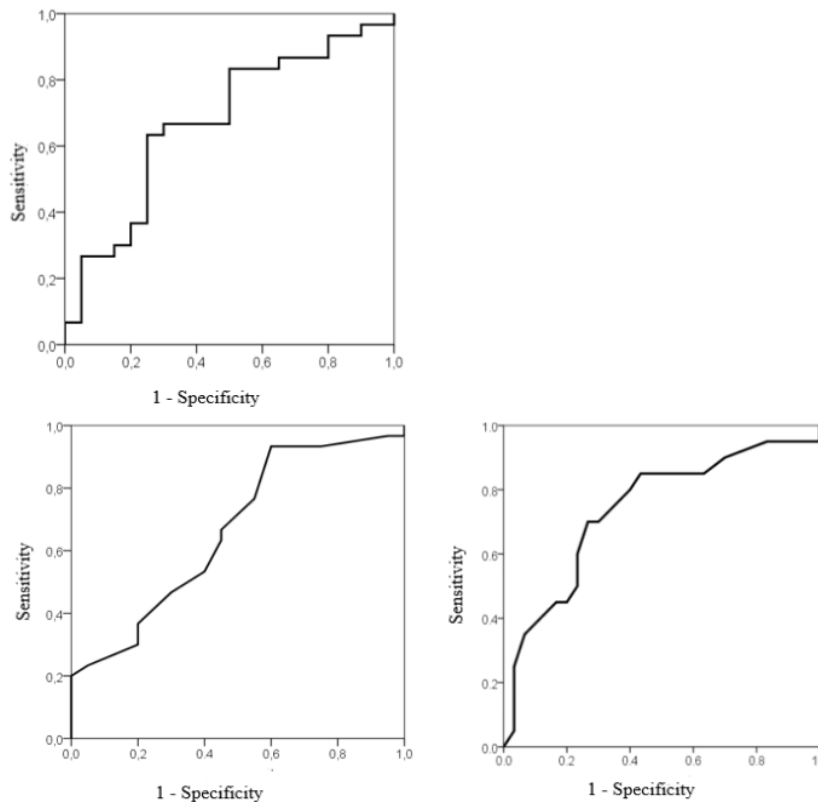


Figure 4: ROC curve of the probability of symptomatic recurrence of AF within the first 12 months after ablation depending on the increase (in percentages) of the bipolar voltage zone 0.05-0.15 mV, p=0.04 (upper left picture); ROC curve of the probability of symptomatic recurrence of AF within the first 12 months after ablation depending on the decrease in unipolar signals at ablation sites, p=0.05 (lower left picture); ROC curve of the probability of symptomatic recurrence of AF depending on the unipolar signals at the ablation sites, p=0.004 (selected ablation site) (lower right picture).

The cut-off limits were a +30% increase in the 0.05-0.15 mV bipolar zone, a -0.4mV decrease in unipolar amplitude at the attached ablation lesions, and greater than 1.23 mV for the mean unipolar amplitude at the ablation sites.

A prognostic model could also be calculated, according to which failure to meet all criteria (+30% increase in the area of the 0.05-0.15 mV bipolar zone, a -0.4mV decrease in unipolar amplitude at the attached ablation lesions, and greater than 1.23 mV for the mean unipolar amplitude at the ablation sites) would be associated with an approximately 67% probability of symptomatic recurrence within the first 12 months. However, if all 3 criteria are met, it is expected to have an approximately 81% success rate.

Discussion

Bipolar mapping is used for diagnostic purposes [16, 17] as well as to guide treatment of AF. [22] This involves measuring the signal amplitude between two sensors located at the LA surface. The extent of bipolar low-voltage areas correlates with the substrate of the AF. [23,24] However, the acquisition of bipolar atrial electrical data is complicated.[18] The vector of activation, angle of the catheter, the size of the sensor, electrode spacing, tissue contact, filtration of signals, and the density of signal acquisition can all impact bipolar amplitudes. [21] As a limit for pathologically altered areas in bipolar mapping, a signal amplitude of <0.5mV is usually set. [25, 17]

The complexity of the examination as well as the decision on therapeutic consequences, ablation strategies and periinterventional success could be simplified and made safe by using some software features of the robotic magnetic navigation system. For this reason, the ablation procedures in the patients studied were performed using the e-Contact module as a quality indicator of catheter tip-to-tissue contact as well as the Ablation History feature, which visually displays a record of the actual energy delivered and accumulated at each ablation site using power output and duration of energy.[26,27]

The use of unipolar mapping in clinical practice is much less common. [28]This mapping method can detect the signals or signal amplitude from a measurement point compared to an indifferent electrode and can be used as an important complement to bipolar mapping [19].

According to the distribution between recurrent (symptomatic, within the first 12 months) and symptom-free patients, the differences occurred in the 0.05-0.15 mV bipolar in both groups, which could be used as a prognostic marker for clinical outcome and ablation procedures.

The unipolar amplitude measured at the ablation points before as well as after ablation changed in a statistically relevant way. Decrease of the signal in all cases by more than 40% is rather to be seen as unrealistic, since greater care must be given to thinner walls to reduce the risk of perforation and collateral damage to adjoining structures. Therefore, we consider the absolute changes in unipolar amplitude to be more usable. The unipolar voltage amplitude at the ablation sites in the patients who suffered a symptomatic recurrence within the first 12 months is lower (1,1 vs 1,4 mV). This could reflect possible fibrosis in the depth of atrial tissues, but could also be used to guide ablation strategy in such patients.

Moreover, the correlation between the energy delivered during ablation and the decrease in unipolar amplitude as well as the relationship between unipolar signals and physical thickness of the atrial wall (e.g., by MRI) and their decrease after ablation and in the long-term course has not yet

been investigated. Such analysis would allow the calculation of therapy delivery goals that optimally balance safety and recurrence rates.

Conclusions

AF is one of the complex diseases in which a therapeutic strategy is equally complicated. At the same time, unipolar mapping provides much information on the sequence of electrical processes in the atrium and correlates with bipolar signals.

High-density mapping provides a great deal of data on the electrical state of the atrium and can both better explain the excitation processes and be an important aid in choosing an ablation strategy. Furthermore, the use of a remote magnetic navigation system offers advantageous technical assets both hardware- and software-wise for improvement of the ablation procedure. First, it enhances safety as no complications occurred during this study and we delivered comparatively low fluoroscopy time during ablation.

Analysis of high-density map including 3 criteria (increase in the area of the 0.05-0.15 mV bipolar zone, a -0.4mV decrease in unipolar amplitude at the attached ablation lesions, and greater than 1.23 mV for the mean unipolar amplitude at the ablation sites), help us to improve ablation success.

Further development of the examination methods - ultra-high-density mapping, would probably provide more in-depth information on the electrical status of the atrium and therefore allow more effective strategies in AF ablation, particularly in complex cases.

List of abbreviations

ACT	:	activated clotting time
AF	:	atrial fibrillation
CT	:	tomography
CAD	:	coronary artery disease
EF	:	ejection fraction
EPS	:	electrophysiology studies
FAM	:	fast anatomical map
LA	:	left atria
LAA	:	left atria appendage
LV	:	left ventricle
LVEF	:	left ventricle ejection fraction
PVI	:	pulmonary vein isolation

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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Conflict of interest disclosure:

- **Yuriy Bychkov** : no financial fee
- **Zdravena Doneva** : no financial fee
- **Björn Buchter** : no financial fee

- **Margarita Kreuzer** : Stereotaxis employee
- **P. Christian Schulze** : no financial fee
- **Burkhard Hügl** : speaker financial fee Biosense Webster

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