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First clinical data on artificial intelligence-guided catheter ablation in long-standing persistent atrial fibrillation

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Abstract

Introduction: Despite advanced ablation strategies and major technological improvements, treatment of persistent atrial fibrillation (AF) remains challenging and the underlying pathophysiology is not fully understood. This study analyzed the multiple procedure outcome and safety of catheter ablation of spatiotemporal dispersions (DISPERS) detected by artificial intelligence (AI)-guided software in patients with long-standing persistent AF.

Methods and Results: The Volta VX1 software was used for 50 consecutive patients undergoing catheter ablation for persistent AF. First, high-density mapping (78% biatrial) with a multipolar mapping catheter was performed. In addition to pulmonary vein isolation (PVI), ablation of DISPERS was performed aiming at homogenizing, dissecting, isolating, or connecting DISPERS areas to nonconducting anatomical structures. Follow-up contained regular visits at our outpatient clinic at 1, 3, 6, and 12 months including 7-day Holter electrocardiograms. Patients were mainly suffering from long-standing persistent AF (mean AF duration 50.30 ± 54.28 months). Following PVI, ablation of left atrial and right atrial DISPERS areas led to AF cycle length prolongation (mean of 162.0 ± 16.6 to 202.2 ± 21.6 ms after) and AF termination to atrial tachycardia (AT) or sinus rhythm (SR) in 12 patients (24%). No stroke or pericardial effusion occurred; major groin complications (pseudoaneurysm $n = 1$, atrioventricular fistula $n = 1$) were detected in two patients. After a blanking period of 6 weeks, recurrence of any atrial arrhythmia was documented in 26 patients (52%). The majority of patients presented with organized AT ($n = 15$) while AF was present in $n = 9$ patients and AT/AF was observed in $n = 2$ patients. Twenty-two patients underwent reablation. During a mean follow-up of 363.14 ± 187.42 days and after an average of 1.46 ± 0.68 procedures, 82% of patients remained in stable SR.

Conclusion: DISPERS-guided ablation using machine learning software (the Volta VX1 software) in addition to PVI in long-standing persistent AF ablation resulted in high long-term success rates regarding AF and AT elimination. Most arrhythmia recurrences were reentrant AT. After a total of 1.46 ± 0.68 procedures, freedom from AF/AT was 82%. Despite prolonged procedure times complication rates were low. Randomized studies are necessary to evaluate long-term efficacy of dispersion-guided ablation using AI.

KEYWORDS

ablation of dispersions, artificial-guided ablation, atrial fibrillation, catheter ablation, high-density mapping

1 | INTRODUCTION

The optimal ablation strategy for patients suffering from persistent atrial fibrillation (AF) is still under debate.[1–3] Pulmonary vein isolation (PVI) is considered the "cornerstone" ablation strategy when treating paroxysmal or persistent AF.[1,4] While PVI is effective in most patients with paroxysmal AF, treatment success in persistent AF remains limited especially in patients suffering from long-standing persistent AF (AF duration > 12 months).[3,5,6] Large randomized trials did not clearly identify a superior ablation strategy to PVI alone in patients suffering from persistent AF.[3,7,8]

Success rates of ablation procedures are influenced by various factors, including patient characteristics, specific ablation techniques, or operator level of expertise. These variables may contribute to the observed variations in success rates across different studies and clinical settings.

The VOLTA VX1 software is an artificial intelligence (AI)-based software solution which was trained using machine learning to detect potentially arrhythmogenic substrate by analyzing electrograms of a large database. The software is able to perform a real-time analysis of detected electrograms and provide the operating physician with information on potentially dispersions (DISPERS) areas. These are subsequently annotated by the operating technician on the mapping system to form the bases of a standard electrogram based ablation procedure. It therefore offers an operator-independent analysis of atrial substrate which could standardize AF ablation procedures. First data on way of operation and using the VOLTA VX1 software in patients suffering from persistent AF were published before.[9,10] To the best of our knowledge, this study provides the first clinical experience on multiple procedure outcome and safety of using spatiotemporal DISPERS-guided ablation additionally to PVI focusing on patients suffering from long-standing persistent AF.

2 | METHODS

2.1 | Study population

In total, 50 consecutive patients undergoing catheter ablation mainly for long-standing persistent AF at the German Heart Center Munich

between May 2021 and January 2023 were included in the study. The study was approved by the local ethics committee. DISPERS-guided ablation was the first AF ablation procedure in 28 patients (56%), while in 22 patients (44%) PVI was performed previously. Patients presenting with atrial arrythmias other than AF at the start of the procedure including left or right atrial flutter, focal atrial tachycardia (AT), atrioventricular (AV)-nodal re-entry tachycardia were excluded from the study. All ablation procedures were guided by the Volta VX1 software additionally to performing high-density electroanatomical mapping.

2.2 | Procedural workflow

Intracardiac thrombus exclusion was performed before ablation using cardiac computed tomography or transoesophageal echocardiography. Direct oral anticoagulants were given continuously. In patients taking phenprocoumon, international normalized ratio was aimed at 2–3, except implanted mechanical valves led to higher target ranges.

The procedure was performed under deep sedation using propofol, midazolam, and fentanyl. Following ultrasound-guided venous groin puncture, a steerable decapolar diagnostic catheter was placed in the coronary sinus. Single transseptal puncture with double access to the left atrium (LA) was performed with a steerable 11.7 Fr sheath (Agilis; Abbott). After transseptal puncture, weight-adapted unfractionated heparin was administered aiming at activated clotting time levels > 330 s.

2.3 | Mapping strategy

A high-density three-dimensional (3D) electroanatomic voltage-map was created with the Advisor HD-Grid mapping catheter and NavX Ensite X system (both Abbott) or with the Pentaray mapping catheter and CARTO3 system (both Biosense Webster).

During mapping, an AI-guided software (VOLTA VX1; Volta Medical) was used to perform real-time analysis of electrograms with spatiotemporal DISPERS, as previously validated by other groups.[9,10] Our clinical setup using the VOLTA VX1 software is identical to the previously described workflow, as shown in Figure 1.[9]
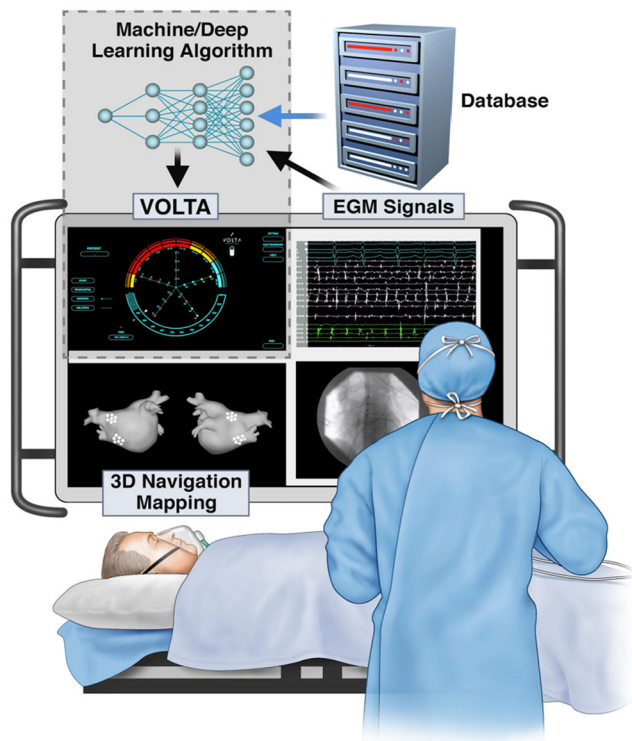
FIGURE 1 Real-life workflow using the VOLTA VX1 software. During mapping, the operator is able to observe fluoroscopy, intracardiac electrograms (EGMs), three-dimensional mapping and the VOLTA VX1 software, which displays temporal and spatial dispersions. In case of detecting dispersions by the software, a technician annotates the localization within the three-dimensional mapping (figure from a previous publication with further technical description[9]). 3D, three dimensional.

2.4 | Ablation strategy

Before ablation, AF cycle length (AFCL) was measured at the left atrial appendage (LAA). Complete wide area circumferential PVI was performed before DISPERS-guided ablation; in case of a redo procedure pulmonary vein (PV) reconnections were identified and reisolated.

Ablation of DISPERS areas was performed in the LA and/or right atrium using an "ablate and connect" approach creating nonconductive barriers as previously described by other groups, aiming to form a homogenous lesion set to reduce the risk for creating potential novel arrhythmogenic atrial substrate.[9–11]

Ablation of all detected DISPERS areas was the endpoint in all procedures within the study. Exception of this endpoint were safety concerns due to proximity of DISPERS areas to the conduction system, possible LAA isolation in case of further ablation and early termination of AF to sinus rhythm (SR) or AT. Operators did not target fractionated areas themselves if areas were not detected by the VOLTA system.

In case of AF termination to an AT, a standard workflow including local activation mapping and entrainment maneuvers was conducted.

In case of absence of AF termination after PVI and ablation at DISPERS areas, LAA cycle length was measured before electrical cardioversion. At the end of the procedure, PV entrance block was tested confirming effective PVI. If a linear lesion set was performed during ablation, bidirectional block was tested with differential pacing. For perimitral flutter, an anterior line connecting the mitral annulus and the left superior PV was performed.

Power controlled, high-power short duration (HPSD) ablation in a point-by-point technique was performed in all patients. Ablation settings varied from 70/7 (anterior wall) to 70 W/5 s (posterior wall) using the FlexabilitySE catheter and from 50/15 (anterior wall) to 50 W/10 s (posterior wall) with the TactiFlex catheter (both Abbott).

When using the Thermocool Smarttouch SF ablation catheter (Biosense Webster) lesions were created with 60/8 (anterior wall) to 60 W/6 s (posterior wall). For linear lesions at the anterior wall, point by point ablation with 50 W/20–25 s was applied with all catheters.

At the end of the procedure, pericardial effusion was excluded with transthoracic echocardiography and all venous sheath were removed following a purse-string suture.

2.5 | Follow up

Before discharge, pericardial effusion was again excluded and ultrasound/Doppler of femoral vessels was performed to rule out AV fistula, pseudoaneurysm or bleeding.

Oral anticoagulation was continued at least 3 months after the procedure, following evaluation of indication for oral anticoagulation using to the CHA_2DS_2-VASc score.

Follow-up visits at the outpatient clinic were scheduled after 1, 3, 6, and 12 months after ablation. Visits included clinical evaluation of patients' past symptoms, a 12-lead electrocardiogram (ECG) as well as a 7-day Holter-ECG during each visit. Any atrial arrythmia documented lasting for longer than 30 s was defined as a recurrence. If a symptomatic recurrence was detected, mode of rhythm control was discussed individually.

2.6 | Statistical methods

For normally distributed metric variables, the statistical mean and standard deviation were used as a measure of central tendency and dispersion within the data set. For variables not normally distributed the median and the range (min–max) were used.

For binary and ordinal variables, absolute and relative frequencies (percent) were expressed.

The Kaplan–Meier method was used to calculate events rates, that is, recurrence rates within the follow-up period. A p value of <.05 was considered significant. The statistical analysis was carried out using SPSS statistics software (IBM SPSS Statistics 27).

3 | RESULTS

3.1 | Baseline characteristics

Mean age of all 50 patients was 67.76 ± 10.64 years and 15 patients (30%) were female. Patients suffered mainly from long-standing AF with a mean AF duration of 50.30 ± 54.28 months and a median AF duration of 34 months (min/max: 1–199). Left atrial ablation including PVI had been performed in 22 patients (44%) whereas in 28 patients (56%) DISPERS-guided ablation was the first AF ablation procedure. Of these 22 patients, 16 had previously undergone one ablation, 4 had previously undergone two ablations, and 2 had previously undergone three ablations.

Mean CHA_2DS_2-VASc score was 3.04 ± 1.73 and class III antiarrhythmic drugs were used in one patient (2%). The mean left ventricular ejection fraction was 51.63 ± 9.97%, mean LA volume index was 52.83 ± 17.58 mL/m^2. Expect for one patient, no other antiarrhythmic drugs besides betablockers were used. Baseline characteristics are shown in Table 1, echocardiographic parameters are illustrated in Table 2.

3.2 | Procedural data and complications

Procedural parameters are also shown in Table 3. Average procedural duration was 182.00 ± 57.13 min with a fluoroscopy time of 9.00 ± 3.53 min. Radiofrequency duration averaged at 28.68 ± 12.67 min. High-density 3D electroanatomical mapping was performed in all patients (in 34 patients [68%] using NavX Ensite X and Advisor HD Grid; in 16 patients [32%] using Carto3 and Pentaray catheter) with biatrial mapping in 39 patients (78%). Reisolation of reconnected PV was necessary in 14 patients who

TABLE 1 Baseline characteristics.

Age, years	67.76 ± 10.64
Women, n (%)	15 (30)
BMI, kg/m^2	26.30 ± 4.34
Hypertension, n (%)	40 (80)
Diabetes mellitus, n (%)	9 (18)
Vascular disease, n (%)	15 (30)
Previous stroke/TIA, n (%)	5 (10)
CHA_2DS_2-VASc score	3.04 ± 1.73
AF duration, months	50.30 ± 54.28
AF ablation in the past, n (%)	22 (44)
Betablocker, n (%)	40 (80)
Amiodarone, n (%)	1 (2)
LV ejection fraction, %	51.63 ± 9.97

Abbreviations: AF, atrial fibrillation; BMI, body mass index; LV, left ventricle; TIA, transient ischemic attack.

TABLE 2 Echocardiographic parameters.

LV ejection fraction	51.63 ± 9.97
LA diameter, mm	45.71 ± 5.26
LA area, mm^2	29.59 ± 6.02
LA volume index, mL/m^2	52.83 ± 17.58
Mitral regurgitation, n (%)	34 (78)
Aortic regurgitation, n (%)	9 (18)
Tricuspid annular plane systolic excursion, mm	17.95 ± 5.49
Systolic pulmonary artery pressure	29.30 ± 10.20
History of cardiac surgery, n (%)	5 (10)

Abbreviations: LA, left atrium; LV, left ventricle.

TABLE 3 Procedural data.

Procedural duration, min	182.00 ± 57.13
Fluoroscopy duration, min	9.00 ± 3.53
Fluoroscopy dose, cGym2	190.96 ± 155.17
RF duration, min	28.68 ± 12.67
Biatrial mapping, n (%)	39 (78)
Termination to AT or SR, n (%)	12 (24)
Termination to SR, n (%)	8 (16)
Baseline AFCL, ms	162.00 ± 16.60
AFCL after ablation of dispersions, ms	202.20 ± 21.63

Abbreviations: AFCL, atrial fibrillation cycle length; AT, atrial tachycardia; RF, radiofrequency; SR, sinus rhythm.

received an AF ablation before DISPERS-guided ablation. PVI was performed in all patients receiving first-time AF catheter ablation (28 patients, 56%). DISPERS-guided ablation using the VOLTA VX1 software was performed in all patients at suggested areas of high dispersion as described in the method section in the LA and right atrium (see Table 4). In 14 patients (28%), at least one linear lesion was created (Table 4). Exemplary high-density mappings are illustrated in Figures 2 and 3.

Termination to AT or SR during the procedure was observed in 12 patients (24%) while direct termination to SR was achieved in 8 patients (16%). Baseline AFCL prolonged from 162.00 ± 16.60 ms before to 202.20 ± 21.63 ms after DISPERS-guided ablation.

Minor groin complications including bleeding and groin hematoma < 5 cm were observed in two patients (4%) and major groin complications (femoral pseudonym, AV fistula) in two patients. No pericardial tamponade or perinterventional stroke occurred. In three patients (6%), temporary pacemaker implantation was necessary but no patient needed permanent pacemaker placement.

TABLE 4 Mapping and ablation data.

First AF ablation procedure, n (%)	28 (56)
Redo procedure, n (%)	22 (44)
Redo PVI necessary, n (%)	14 (28)
3D mapping system and mapping catheter	
NavX Ensite X/Advisor HD Grid, n (%)	34 (68)
Carto3/Pentaray, n (%)	16 (32)
Location of DISPERS-guided ablation, n (%)	
Anterior LA	47 (94)
Posterior LA	46 (92)
LA roof	31 (62)
LAA base	18 (36)
Lateral LA	11 (22)
Anterior RA	19 (38)
Crista terminalis	15 (30)
Ostium of the coronary sinus	9 (18)
Linear lesions after completion of DISPERS ablation	
Anterior line, n (%)	6 (12)
Roof line, n (%)	12 (26)
Posterior wall isolation, n (%)	2 (4)
CTI line, n (%)	4 (8)

Abbreviations: AF, atrial fibrillation; CTI, cavotricuspid isthmus; DISPERS, dispersions; LA, left atrium; LAA, left atrial appendage; PVI, pulmonary vein isolation; RA, right atrium.

3.3 | Follow-up and long-term success

The total follow-up duration was 363.14 ± 187.42 days with a mean follow-up after the last ablation of 279.04 ± 175.39 days.

After a blanking period of 42 days, 24 patients (48%) maintained stable SR after receiving the first DISPERS-guided ablation and 78% of patients remained free from AF (Figures 4 and 6).

In total, arrhythmia recurrences were documented in 26 patients (52%). The majority of patients presented with organized AT (n = 15) while AF was present in n = 9 patients and AT/AF was observed in n = 2 patients (Figure 5).

Twenty-two out of 26 patients (84.6%) with an arrhythmia reccurence after the blanking period received reablation. Five out of 22 patients suffered paroxysmal AT or AF recurrences. All four patients without a reablation at the time of publication suffered a recurrence of AF.

Overall, multiple procedure success rate (patients in stable SR) after a mean of 1.46 ± 0.68 ablation procedures following the first DISPERS-guided ablation was 82% (Figure 6). When including previous ablation procedures before DISPERS-guided ablation a mean of 2.10 ± 0.95 ablation procedures were performed. Overall

freedom from AF after multiple ablation procedures was 88% within the follow-up period.

3.4 | Repeat ablations

Twenty-two patients received a second ablation after initial DISPERS-guided ablation. From 11 patients presenting with AF, 4 patients received further electrogram-based substrate modification (not AI-guided). One patient presented with roof-depended atrial flutter at the time of reablation. In two patients with paroxysmal AF recurrences, re-PVI and an anterior line and a roof line was created as scarred tissue at the anterior wall and at the roof was observed. Four patients did not undergo further ablation despite a recurrence.

In the remaining 15 repeat procedures organized AT was the underlying mechanism. Six patients suffered from perimitral flutter and were treated with an anterior line and two patients received ablation of the CTI due to typical atrial flutter. PV-depended atrial flutter was observed in two patients, localized reentries (LR) were ablated in two patients (LR at the roof and anterior LA wall). Two patients presented with roof-depended atrial flutter. Electrogram-based substrate modification was performed in one patient, as the AT was not stable and degenerated into AF.

4 | DISCUSSION

The present study provides first clinical experience of DISPERS-guided ablation using the AI-based VOLTA VX1 software exclusively in patients suffering from long-standing persistent AF.

In this study, DISPERS-guided ablation additionally to PVI resulted in high 12-month success rates regarding AF elimination using an individualized stepwise AF ablation approach.

Catheter ablation in patients suffering from persistent AF remains challenging with single procedure success between 50% and 60% in large randomized study's.[2,3,5,7] In patients suffering from long-standing persistent AF success rates are likely to be lower.[12,13] The ideal ablation strategy in addition to PVI for patients with persistent AF remains to be determined and is an ongoing topic of debate. The STAR AF II trial prospectively randomized 589 patients to either PVI alone or to PVI and additional ablation of electrograms showing complex fractionated activity or additional ablation of linear lesions in the LA. The investigators found no reduction of recurrence rates in the groups of additional left atrial ablation compared to PVI alone.[3]

The recently published CAPLA randomized trial also failed to demonstrate superiority of additional ablation in the form of posterior left wall isolation to PVI alone in patients suffering from persistent AF.[7] On the other hand, trials such as the ERASE-AF trial published in 2022 provide important insights on the potential benefit of individualized substrate ablation of left atrial low voltage areas in addition to PVI alone.[8]
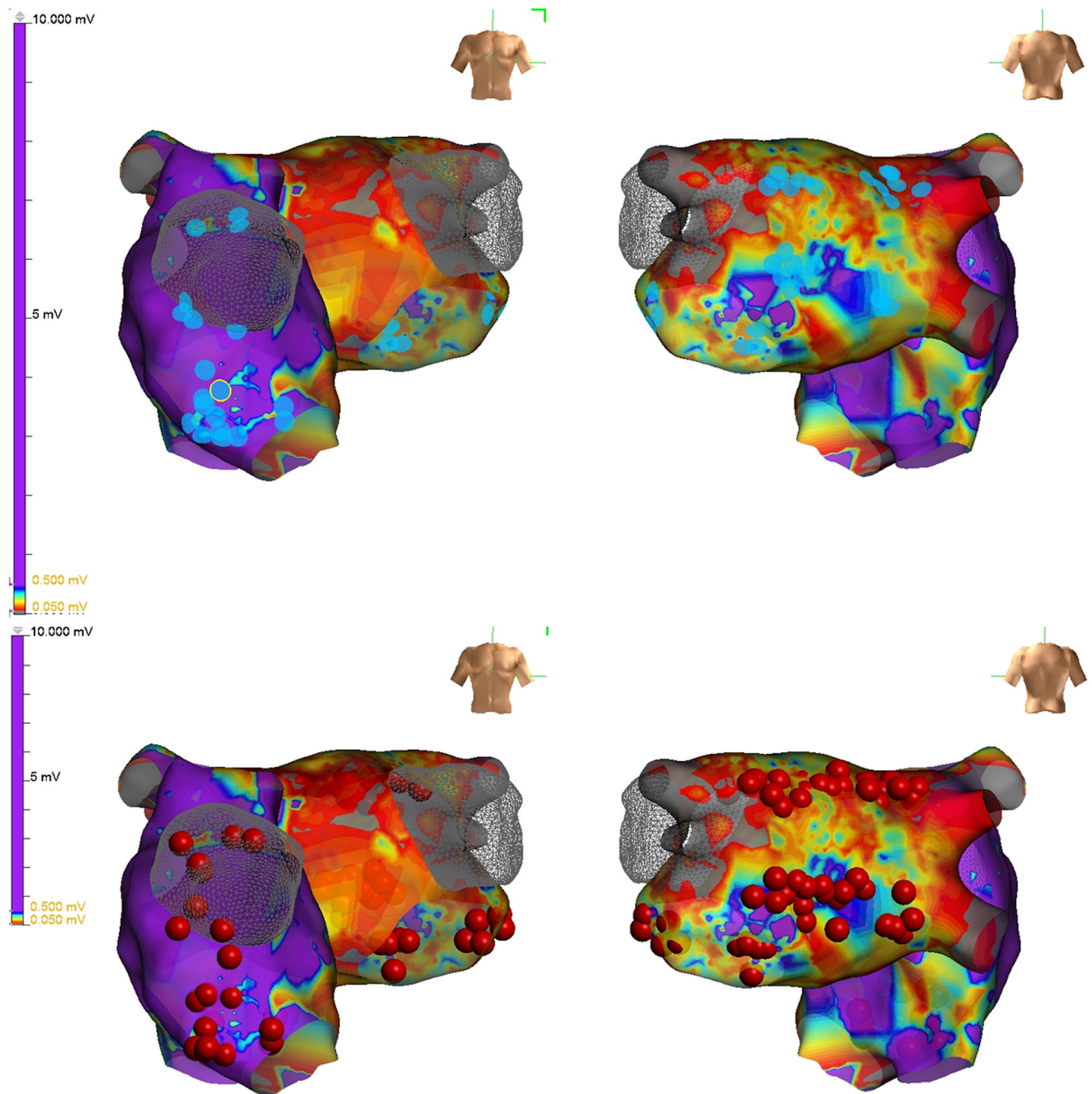
FIGURE 2 Exemplary voltage maps illustrating individual distribution of DISPERS areas (blue dots) and consecutive ablated areas (red dots). In this case, pulmonary veins were isolated after previous ablation. A roof line was created due to detected DISPERS areas at the LA roof. Additionally, DISPERS areas in the LA and right atrium were ablated. Notably, no relevant DISPERS areas were detected at the anterior LA wall. DISPERS, dispersions; LA, left atrium.

In patients suffering from long-standing persistent AF, PVI alone is unlikely to provide an effective ablation strategy to achieve long-term freedom of atrial arrhythmia and more individualized and operator independent ablation approaches seem necessary.

The recent rise of machine learning based software within the medical field offers great potential for application in cardiac electrophysiology and leads to the development of a novel machine learning based software (VOLTA VX1) to guide additional substrate ablation in patients suffering from AF.[14]

In 2017, Seitz et al. described intracardiac electrograms which display spatial and temporal DISPERS when collected with a multipolar Electrograms as potential AF drivers.[10] They hypothesized that a selective targeted ablation of DISPERS areas and thus
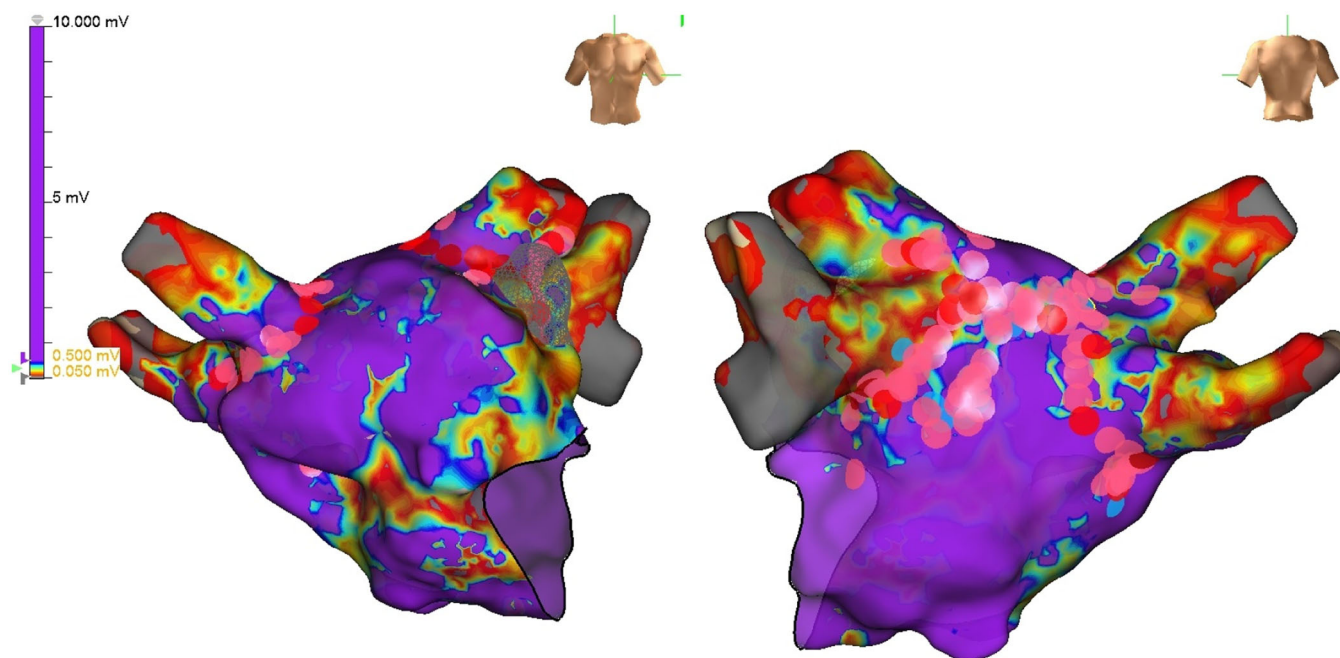
FIGURE 3 Exemplary voltage map including detected DISPERS areas and ablation lesions. A PVI was performed at the beginning of the procedure. Subsequently, a roof line connecting the PVI circles was created because of DISPERS areas at the LA roof. Notably, no other DISPERS areas were observed in this case in the LA. Bidirectional block of the roof line was observed. DISPERS, dispersions; LA, left atrium; PVI, pulmonary vein isolation.
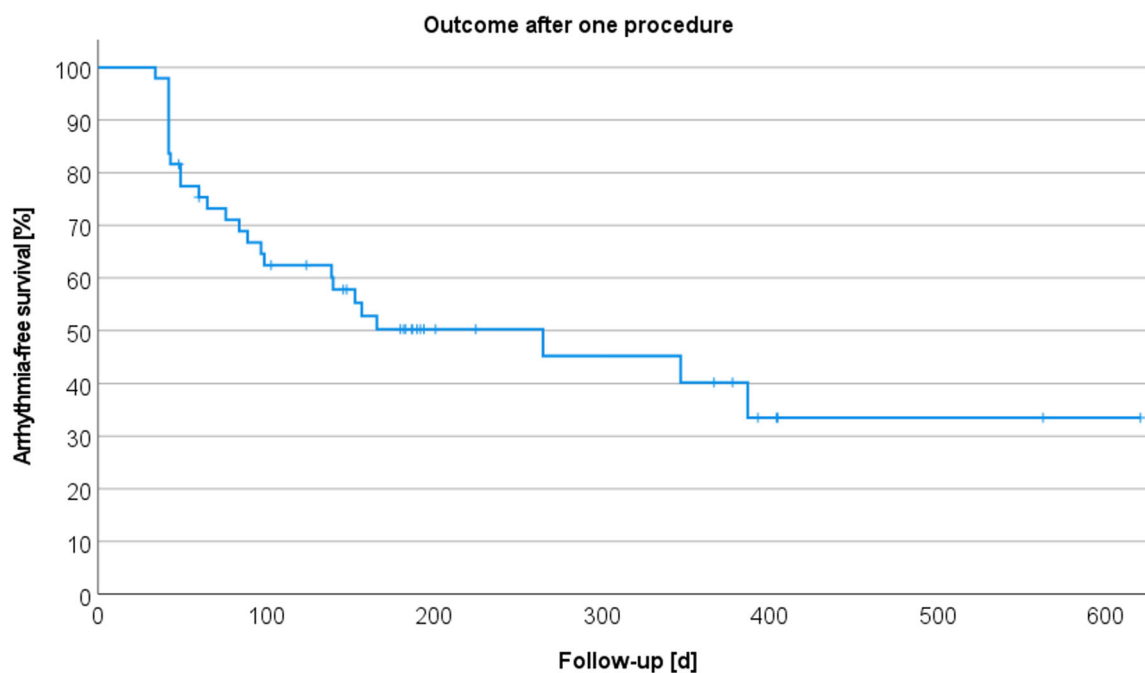
FIGURE 4 Single procedure outcome after DISPERS-guided ablation. A Kaplan–Meier curve illustrates arrhythmia-free survival in all patients (n = 50) after the first DISPERS-guided catheter ablation. DISPERS = spatiotemporal dispersions. DISPERS, dispersions.

elimination of AF drivers leads to a more individualized ablation approach with potential for a superior outcome.[10]

A study from 2022 of the same group described the usage of a novel AI-based software solution (VOLTA VX1) to reliably identify atrial DISPERS areas for the first time. In their study which enrolled 85 patients suffering from persistent AF, freedom from AF was 86% after a single procedure, and 89% after an average of 1.3 procedures.[9] Freedom of any atrial arrhythmia was achieved in in

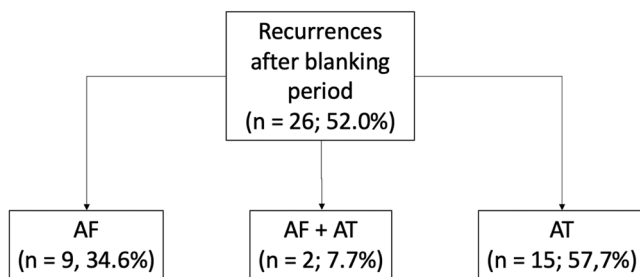54% after a single procedure and 73% after an average of 1.3 procedures.[9]

The present study focusing mainly on patients suffering from long-standing persistent AF showed high rates of AF elimination in 78% of patients after a single procedure and 88% freedom from AF after multiple procedures. Nevertheless, clinically more relevant is freedom from any atrial arrhythmia. Within the follow-up period, this endpoint was observed in 82% of patients after an average of 1.46 ± 0.68 procedures. Importantly, only 26% of patients included in the analysis conducted by Seitz et al. suffered from long-standing persistent AF which may explain the higher overall success rates when compared to our data.[9]

In our study, freedom from AF after a single DISPERS procedure was high but many patients suffered from AT within the follow-up period. Similar to other ablation approaches that involve any form of substrate-based ablation, DISPERS ablation is considered as "step-wise" where long term arrythmia freedom can only be achieved by sequential ablations.[15–17]

A procedural duration of 182.00 ± 57.13 min is still considered long when compared to standard PVI duration in experienced centers using a HPSD ablation approach.[18,19] This is due to a longer mapping time when analyzing DISPERS areas as well as the subsequent additional ablation time. However, a learning effect and a more routine system implementation is likely to reduce overall procedure duration significantly over time.
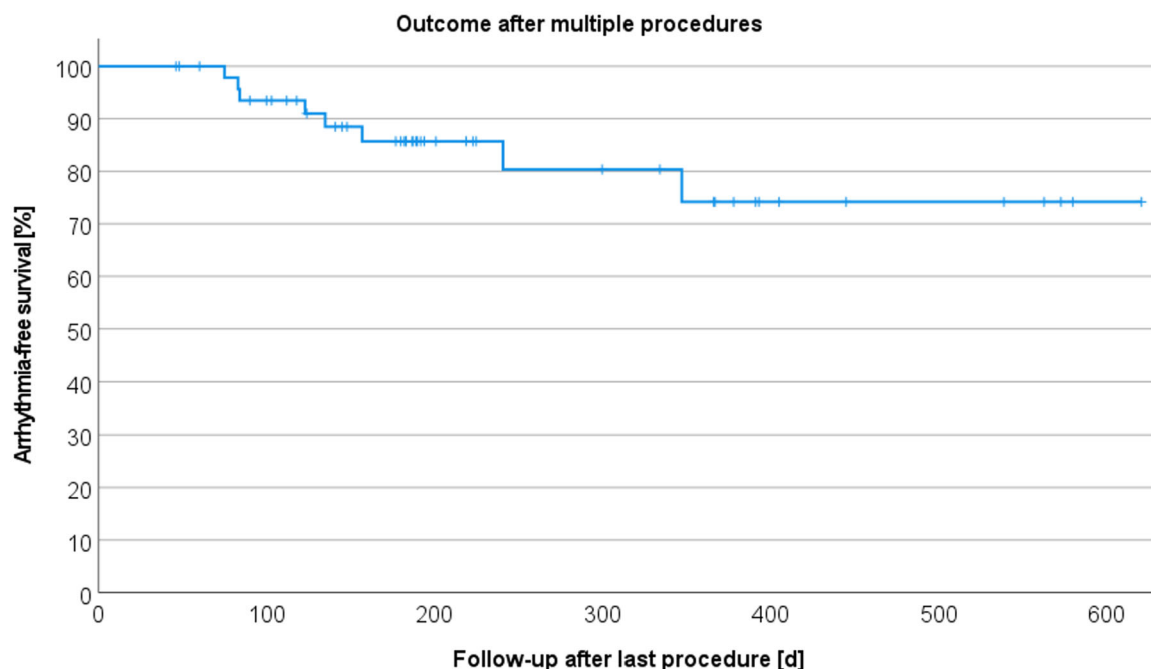
Overall, our study offers a first clinical experience using a novel AI-based software to guide a more individualized stepwise AF ablation approach in patients suffering from long-standing AF. The results offer a promising outlook of the potential use of machine learning in cardiac electrophysiology to better understand and thus eliminate complex atrial arrhythmias.

4.1 | Limitations

Due to the nature of this study the results should be considered hypotheses generating leading the way for larger randomized trials. The study is a retrospective and nonrandomized single center experience with a relatively small patient population. In 44% of patients previous PVI had been performed resulting in a potential selection bias. To reduce this bias, (re-) PVI was chosen as a starting point for DISPERS-guided ablation in all patients. All procedures were performed by experienced operators. However, we cannot rule out a potential learning effect over time when using the VOLTA VX1 system.

FIGURE 5 Mode of arrythmia recurrence after blanking period of 42 days. Twenty-six patients suffered a recurrence of either atrial fibrillation (AF) (34.6%) or left atrial tachycardia (AT) (57.7%). In two patients, AF and AT were observed during follow-up.

FIGURE 6 Multiple procedural success after DISPERS-guided ablation. Kaplan–Meier curve illustrates the outcome after multiple procedures after the initial DISPERS-guided ablation. DISPERS = spatiotemporal dispersions. DISPERS, dispersions.

Due to the retrospective nature of the study follow up is limited and larger trials are necessary to evaluate long-term procedural success.

In this study, we deliberately investigated patients mainly suffering from long-standing persistent AF, a patients' group with limited ablation success which is in our view underrepresented in most large randomized trials. AF durations before ablation are lower in most large randomized trials and we therefore believe it is difficult to directly compare these results with the patient population of our study.

DISPERS-guided ablation using the VOLTA system offers a more standardized approach. However, similar to other electrogram-based ablation strategies interoperator differences are difficult to rule out completely. For this study our group independently evaluated the Volta VX1 software and thus we cannot provide any additional information on the underlying algorithm detecting spatiotemporal DISPERS.

5 | CONCLUSION

DISPERS-guided ablation using AI-based software additionally to PVI yielded in success rates of 82% regarding freedom of AF or AT after a total of 1.46 procedures. Most arrhythmia recurrences were macroreentrant AT. Despite prolonged procedure times, complication rates remained low. However large randomized studies are necessary to evaluate long-term efficacy of dispersion-guided ablation using AI in patients suffering from persistent AF.

DATA AVAILABILITY STATEMENT
Research data are not shared.

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