Minielec trode catheter technology for near zero-fluoroscopy substrate-guided ablation of typical atrial flutter

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BACKGROUND MicroFidelity catheter technology may facilitate voltage-guided ablation by high-resolution electroanatomic mapping (HR-EAM) and precisely targeted energy application.

OBJECTIVE To evaluate the performance of minielec trode (ME) technology for zero-fluoroscopy substrate-guided cavotricuspid isthmus (CTI) ablation.

METHODS Eighty-two patients underwent near zero-fluoroscopy substrate-guided CTI ablation using a nonirrigated large-tip catheter with 3 MEs. The CTI was subdivided into 15 electroanatomic segments. Bipolar voltage maps were compared with ME signals. The outcome was compared with a historic cohort of 92 patients who underwent linear ablation.

RESULTS Compared with linear ablation, the substrate-guided approach was associated with an almost halved ablation duration (336 ± 228 vs 649 ± 409 seconds, \( P < .001 \)), halved radiofrequency energy applied (14.2 ± 10.6 vs 28.6 ± 19.6 kJ, \( P < .001 \)), and shorter procedure duration (60.8 ± 33.8 vs 76.3 ± 40.9 minutes, \( P = .008 \)) limiting the extent of energy delivery to 22.7% of the CTI area. HR-EAM visualized 2.03 ± 0.88 conductive pathways with a diameter of 5.35 ± 1.98 mm. A higher number of ME-detected bundles and a larger channel diameter correlated with increased ablation requirements. In 97.6% of the voltage-guided and 88.0% of the linear procedures, fluoroscopy was not used.

CONCLUSION HR-EAM-based substrate-guided CTI ablation may improve procedural outcome compared with the linear approach. Enhanced identification of discrete conductive pathways correlates with ablation efficacy. The electroanatomic subdivision of the CTI into 15 segments was feasible and may improve the understanding and comparability of anatomic variants and ablation results. Independent of the ablation strategy, modern EAM technology enables safe zero-fluoroscopy procedures in the majority of cases.

KEYWORDS Atrial flutter; Catheter ablation; Electroanatomic mapping; Maximum voltage-guided; Zero fluoroscopy

Introduction

Radiofrequency catheter ablation of the cavotricuspid isthmus (CTI) represents the first-line treatment for typical atrial flutter (AFL). Although its efficacy is high, the conventional ablation is still time-consuming and requires a considerable amount of radiation, and treatment failure occurs.

The maximum voltage (MV)-guided (MVG) approach aims to identify and selectively ablate conductive muscle fibers. Therefore, accurate identification of MV areas and precisely targeted radiofrequency energy (RFE) application are decisive factors. Although a reduction of ablation requirements has been shown, the current evidence is still considered to not be robust enough to suggest a general change in the ablation strategy. In addition, there are conflicting data regarding fluoroscopy time (FT).

MicroFidelity sensor technology (Boston Scientific, North Quincy, MA) was developed to enhance spatial resolution of large-tip catheters using 3 minielec trodes (ME) with a diameter of 1.2 mm radially integrated into the distal tip. By reducing the gap between the origin of high-resolution (HR) signals and the center of RFE application, this technology may facilitate MVG ablation. The goal of this study was to evaluate the procedural performance of the ME for zero-fluoroscopy substrate-guided CTI ablation.

Methods

Study population

Two-hundred ninety consecutive patients underwent CTI ablation for documented typical AFL between June 2016
and October 2019. All patients provided informed consent for the intervention and data documentation. The study was performed according to the requirements for obtaining the medical degree (Dr. med.), is approved by the responsible ethics committee, adhered to the Declaration of Helsinki, and is registered at the German Registry for Clinical Trials (DRKS00020533). Patients with implanted cardiac devices (n = 21), previous CTI ablation (n = 18), nonconvertible atrial fibrillation (n = 1), concomitant pulmonary vein isolation (n = 43), and a different catheter setting (n = 33) were excluded from this analysis. Therefore, study group 1 consisted of 82 prospectively enrolled patients undergoing MVG ablation using the ME catheter since September 2017 and was compared to a historic group of 92 patients treated with conventional linear CTI ablation between June 2016 and November 2018 (group 2). These groups were not different regarding baseline characteristics (Table 1).

Electrophysiological study
Two decapolar catheters were each positioned in the coronary sinus and along the tricuspid valve annulus (TVA). A 3-dimensional electroanatomic mapping (EAM) system (EnSite Velocity™, since 2018 Precision™; Abbott, St Paul, MN) was used for catheter positioning, mapping, and ablation in all procedures. Mapping and ablation were conducted either during ongoing flutter or, when presenting in sinus rhythm, during pacing from the proximal coronary sinus.

Group 1: MVG/ME
The MVG approach was performed using the nonirrigated 8-mm IntellaTip MiFi XP™ catheter (Boston Scientific). Both conventional distal bipolar (CDB) signals and bipolar electrograms from all ME were recorded simultaneously along the inferior CTI using the EnSite AutoMap module (Figure 1). Local peak-to-peak amplitudes were visualized in a bipolar voltage map first (point border interpolation 5–7). Besides tagging the point of MV, color-coding was set to mark areas with ≥70% of the measured MV as conductive bundles initially. The color threshold could be adapted according to the individual voltage characteristics for best bundle identification. Thereafter, a second voltage map was created using the EnSite TurboMap feature for automated analysis of the ME signals deriving from the original mapping dataset at 10× real-time speed. The CTI was subdivided into 15 sections as shown in Figure 1. Following a stepwise voltage-guided approach, RFE (60 W/60°C) was applied for 20–60 seconds according to the local amplitude reduction, beginning at the point of MV recorded by ME mapping, and continued at areas with ≥70% of the measured MV. If no bidirectional conduction block (BCB) was achieved, the voltage border was gradually reduced to identify adjacent areas with higher voltage, possibly representing larger conduction channels. Further, RFE was applied at these spots. In case of continued inefficacy, a re-map was performed and RFE delivery was extended to sites showing residual slow conduction. Ultimately, the operator could proceed to linear ablation.

Group 2: Conventional approach
Patients in group 2 underwent standard EAM-guided linear CTI ablation as described elsewhere in detail. The nonirrigated 8-mm-tip catheter HF-Contact™ (Medtronic, Minneapolis, MN) and Therapy™ (large or X-large curve; Abbott) were used for temperature-controlled ablation (50–60 W, 50–60°C) in 56 (61%) and 36 patients (39%), respectively. The procedural endpoint for both groups was BCB with established characteristics, persisting after a waiting period of 30 minutes.

Follow-up
All patients underwent postinterventional echocardiography and telemetric monitoring for 24 hours. Clinical follow-up including Holter monitoring was performed by the outpatient clinic or the referring cardiologist.

Statistical analysis
A minimum sample size of 59 patients per group was required to detect a 35% difference in cumulative ablation.
duration between both ablation strategies (main hypothesis) with a statistical power of 90% at a 2-sided 5% significance level, including an addition of 15% owing to planned use of a nonparametric test. Results are presented as means ± standard deviation or median and interquartile range. Continuous variables were compared by unpaired t test or Mann–Whitney U test for normally and non-normally distributed data, respectively. The χ² test or Fisher exact test was used for nominal variables. Correlation of continuous variables was assessed by Pearson correlation coefficient. A P value < .05 was considered statistically significant.

Results
Procedural outcome
Procedural outcome is shown in Table 2. Acute success was achieved in 80 patients (97.6%) undergoing MVG ablation and in 87 patients (94.6%) in group 2 (P = .449).

Compared with the linear approach, voltage-guiding significantly reduced ablation duration (336 ± 228 vs 649 ± 409 seconds, −48.2%, P < .001, Figure 2), RFE (14.24 ± 10.58 vs 28.58 ± 19.58 kJ, −50.2%, P < .001), and the number of ablation points (7.82 ± 6.08 vs 11.38 ± 9.79, −31.3%, P = .010). Additional ablation owing to acute

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Table 2  Procedural outcome according to ablation strategy

| Variable                        | Linear n = 92 | MVG/ME n = 82 | P value |
|---------------------------------|--------------|---------------|---------|
| Acute ablation success          | 87 (94.6%)   | 80 (97.6%)    | .449    |
| Cumulative ablation duration (s)| 649 ± 409    | 336 ± 228     | <.001   |
| Radiofrequency energy (kJ)      | 28.58 ± 19.58| 14.24 ± 10.58 | <.001   |
| Number of ablation points       | 11.38 ± 9.79 | 7.82 ± 6.08   | .010    |
| Procedure duration (min)        | 76.3 ± 40.9  | 60.8 ± 33.8   | .008    |
| Minor complications, total      | 5 (5.4%)     | 4 (4.9%)      | 1.000   |
| Groin hematoma                  | 2 (2.2%)     | 4 (4.9%)      | .423    |
| Pop phenomenon                  | 2 (2.2%)     | 0             | .499    |
| Agitation under sedation        | 1 (1.1%)     | 0             | 1.000   |
| Zero-fluoroscopy procedures     | 81 (88.0%)   | 80 (97.6%)    | .011    |
| Fluoroscopy time (min)          | 0.3 ± 1.2    | 0.1 ± 1.2     | .018    |
| Effective dose (µSv)            | 12.21 ± 50.81| 2.59 ± 23.30  | .010    |
reconnection during the waiting period was needed in 13 cases of the MVG group (15.9%) compared with 8 patients undergoing linear ablation (8.7%; \( P = .148 \)). Four patients from group 1 (4.9%) required complete linear ablation, resulting in BCB in 2 of them. Despite requiring additional time of 8.1 ± 7.0 minutes for voltage mapping, the procedure duration was shorter in the MVG/ME group (60.8 ± 33.8 minutes vs 76.3 ± 40.9 minutes, \( -20.3\%, \ P = .008 \)).

No major complications occurred. Nine minor adverse events were documented (Table 2).

**Radiation exposure**

A total of 161 procedures (92.5%) were performed without fluoroscopy (97.6% MVG, 88.0% linear), as shown in Table 2. The rate of minor complications was not different between fluororless ablation (3.7%) and procedures requiring minimal fluoroscopy (7.7%, \( P = .425 \)).

**High-resolution voltage-guiding**

Data for CDB and ME maps derive from 407 ± 280 and 1209 ± 1027 collected CTI points, respectively. In general, the local MV measured with the ME was higher compared with bipolar signals (9.1 ± 3.4 vs 4.3 ± 2.2 mV, \( P < .001 \)). High-voltage areas (HVA, ≥70% of MV) were found predominantly in central segment C3, followed by C2/4, for both CDB and ME signals (Table 3). ME-based EAM visualized a mean of 2.03 ± 0.88 conductive routes with a diameter of 5.35 ± 1.98 mm compared with 1.41 ± 0.53 pathways for CDB mapping.

In total, 209 ablation points were documented, with the majority set in section C3 (n = 42, 20.1% of all documented ablation points), followed by section C4 (n = 33, 15.8%). The fewest points were applied in the septal column and near the TVA (Table 3).

For ME-based mapping, a higher MV correlated with lower RFE for BCB (\( r = -0.265, \ P = .041 \)). A higher number of ME-detected conducting pathways and a larger channel diameter correlated with increased RFE, ablation duration, and number of ablation points to BCB. No correlation was found for CDB-detected channels (Table 4; Figure 3).

Voltage guiding enabled to achieve a BCB with RFE delivery at only 22.7% of the entire CTI area (3.4 sections...
Follow-up
During a median follow-up of 12 months (interquartile range 0.5–34.9 months), there were 8 clinical recurrences of CTI-dependent AFL in the linear group (8.7%) after a median time of 101 days between ablation and recurrent flutter compared with 4 patients (4.9%, 98.5 days) after MVG ablation ($P = .381$). In all patients CTI reconduction was confirmed and reablated successfully.

Seventeen patients without clinical AFL recurrence (11 linear, 6 MVG) underwent a second electrophysiological study for atrial fibrillation ablation. Recurrent CTI conduction was documented and reablated in 2 patients of the linear group (18%) and 1 patient (17%) after MVG ablation ($P = \text{not significant}$).

Discussion
Main findings
Main findings were as follows: (1) Substrate evaluation and identification of discrete conductive pathways may be significantly improved by ME-based HR-EAM and is correlated with ablation efficacy. (2) Using full-automated EAM features for precise ME-guided substrate ablation reduces procedure duration and almost halves ablation time, as well as applied energy, compared with linear ablation. (3) Together with high-resolution mapping, electroanatomic subdivision of the CTI into 15 segments may support the understanding and comparability of individual electroanatomic characteristics. This may further improve the results of targeted ablation. (4) Independent of the ablation strategy, modern EAM enables safe zero-fluoroscopy CTI ablation in the majority of procedures.

Electroanatomic CTI classification
For anatomic description, the CTI has been subdivided into 3 parallel levels, namely, a central inferior, paraseptal, and inferolateral isthmus. In the posterior–anterior direction, the anterior myocardial vestibule near the TVA is distinguished from a middle trabeculated part and a posterior membranous sector. We introduced an electroanatomic subdivision of the CTI into 15 segments with 5 central sectors corresponding to the inferior isthmus bordered by 5 paraseptal and 5 inferolateral segments (Figure 1). The simple visual segmentation could be easily estimated and used by the operator while performing the procedure. For CTI ablation based on the individual electroanatomy aiming for limited and precisely targeted energy application, the approximative CTI segmentation was found to be feasible and helpful, allowing standardized description and comparison of both mapping and ablation results.

Automated EAM for individual substrate-guided ablation
The CTI exhibits a unique but variable architecture of muscular bundles separated by intervening connective tissue. The MVG approach directly targets muscle bundles identified by local high-voltage electrograms. Reproduced by many other working groups, the concept was proven by Gula and colleagues in 2006 and 2009, showing a significant reduction of ablation requirements for the MVG approach compared with linear ablation. However, no correlation was found between the initial CTI voltage and ablation

| Conductive channels, conventional bipolar signals | Conductive channels, minielectrode signals | Mean diameter of minielectrode-detected channels |
|------------------------------------------------|------------------------------------------|-----------------------------------------------|
| Cumulative RFE | $r = 0.219, P = .089$ | $r = 0.292, P = .022$ | $r = 0.884, P < .001$ |
| Ablation duration | $r = 0.206, P = .112$ | $r = 0.315, P = .013$ | $r = 0.866, P < .001$ |
| Number of ablation points | $r = 0.147, P = .257$ | $r = 0.261, P = .042$ | $r = 0.802, P < .001$ |

RFE = radiofrequency energy.

Figure 3  Correlation between the mean diameter of conductive cavotricuspid isthmus pathways detected by minielectrode (ME)-based electroanatomic mapping and ablation parameters ($n = 61$).
requirements that could be explained by less effective lesions applied at previously ablated sites. Without using nonfluoro-
soscopic EAM, the mapping strategy was continuous signal amplitude measurement during initial pull-back, to note and to ablate the site with MV, followed by remapping and further targeting the remaining MV. The additional time needed for repeated mapping prior to each ablation prevented further reduction of procedure duration and FT (86 ± 50 vs 92 ± 53 minutes and 25 ± 14 vs 23 ± 13 minutes for MVG vs linear ablation, respectively).

In contrast to previous strategies, our mapping approach aimed not only to note and target the maximum voltage, but to characterize the individual native CTI electroanatomy and to identify distinct conduction routes as ablation targets based on native HR signals. With respect to the interindividual variations in the CTI anatomy and voltage, we used all signals showing a threshold of ≥70% of the detected individual MV for initial electroanatomic assessment both in the conventional bipolar and the ME maps instead of a fixed general cut-off for measured voltage, as used by Sato and colleagues. In cases with large uniform HVA or no demarcation of bundles, the initial threshold was gradually modified to improve bundle visualization. An advantage of this approach is the individually adopted initial assessment

Figure 4 Voltage-guided ablation, complex cavitricuspid isthmus (CTI) electroanatomy, zero-fluoroscopy. A: EnSite Precision (Abbott, St Paul, MN) map during CTI-dependent atrial flutter, caudal view, 6 o’clock. Left: conventional bipolar voltage-AutoMap showing a single conduction pathway (white borders) with a central high-voltage area of 8 mm² (segments C3/4, maximum voltage [MV] 7 mV, blue borders). Right: Minielectrode-TurboMap showing an additional conductive bundle in the more anterior segments 2 (MV 8.2 mV, black borders) and the bundle connection. B: Treatment: Initial ablation of the central bundle prolonged the cycle length and terminated the flutter but without bidirectional conduction block (BCB). Successively targeting the anterior pathway resulted in BCB (turquoise dot). Left: right anterior oblique view; right: caudal view, 6 o’clock. Yellow dots = His bundle; inferior brown dots = CTI length; cranial brown dot = patent foramen ovale.
of the native electroanatomy before changing signal characteristics by ablation, thus avoiding repeated mapping and assessment of altered signals. The strategy was helpful in particular in cases with complex anatomy when the first RFE applications failed to block. Consequently, in this study, the almost halved ablation time achieved by MVG ablation could be translated into a significant reduction in procedure duration.

ME-based CTI mapping for bundle identification

The ME technology was developed to improve the spatial mapping resolution of large-tip catheters.\textsuperscript{15,21}

To the best of our knowledge, we evaluated the largest population so far of patients undergoing zero-fluoroscopy MVG ablation based on ME 8-mm-tip catheter mapping, providing comprehensive data on intra- and interindividual comparisons of simultaneously recorded conventional bipolar and ME signals.

Besides showing signals with higher amplitude and sharper configuration, the increased spatial resolution of the ME, together with an individualized EAM approach, allowed direct visualization and differentiation of distinct conductive pathways (Figure 4).

Of course, it is important to note that the distance measured for conductive routes in the voltage map is not necessarily equal to the diameter of anatomical bundles and may vary depending on the mapping settings used. However, using the investigated mapping approach, it was possible to visualize even distinct oblique conductive pathways connecting other bundles, explaining the observed phenomenon of central ablations failing to achieve BCB despite effective RFE delivery and local signal amplitude reduction (Figures 1 and 4). For the first time, we were able to demonstrate a linear correlation of the CTI electroanatomy detected by ME signals with ablation parameters (Figure 3), hereby proving the clinical feasibility of substrate-focused CTI ablation.

It has been shown that ME may be helpful to avoid unnecessary ablation, especially at the annular part of the CTI.\textsuperscript{22} This seems to be in contrast to anatomic studies showing thickest bundles in the anterior segments\textsuperscript{18} and to findings from Shah\textsuperscript{23} demonstrating relevant gaps near the TVA. In our study, careful EAM found a local voltage of ≥70% MV in the anterior segments in ≤4% for both CDB and ME signals (Table 3). Targeting HVA first, ablation near the TVA was needed only in 4.8%. A possible explanation may be the anatomical course of oblique or longitudinal muscle bundles passing from the middle to the anterior segments terminating on the hinge of the TVA.\textsuperscript{18} These anatomic bundles must not be necessarily essential for CTI conduction and—if conductive—may often be effectively ablated in the middle sector when using the MVG approach.

In accordance with Tzeis and colleagues,\textsuperscript{15} we found ME mapping useful and superior to CDB signals for assessing the proximal sections near the IVC. Ablation of a muscular Eustachian ridge was needed in 8 patients of the MVG group (13.1%), corresponding to 13.4% of the ablation points applied.

In an important comment, Caldwell and colleagues\textsuperscript{24} stressed occasional difficulties in achieving BCB using the conventional approach of repeated remapping during pull-back following RFE application, based on the fact that ME mapping guides the ablation focus more proximal compared with conventional bipolar electrodes. In our study, we also did experience an improved ablation efficacy when placing the large tip of the MiFi XP catheter about 2 mm more distal, following the idea of better covering the bundle displayed by the ME signals and improving tissue contact.

Zero-fluoroscopy CTI ablation

Mol and colleagues\textsuperscript{25} suggested using ME to avoid a 3-dimensional navigation system. The approach was associated with a fluoroscopy duration of 18 minutes. On the other hand, there is growing evidence that modern mapping technology and targeted strategies allow for significant reductions of FT.\textsuperscript{22,26,27}

Deutsch and colleagues\textsuperscript{9} reported a non-fluoroscopy approach for 91% and 93% of the patients undergoing MVG or linear ablation. The results from our study reproduce these findings, showing a zero-fluoroscopy rate of 92.5% irrespective of the ablation strategy. Thirteen of 174 procedures required an FT of 0.3 ± 1.2 minutes in the linear and 0.1 ± 1.2 minutes in the MVG group, which is nearly identical to the findings from Deutsch and colleagues. The maximum effective dose was 0.34 mSv in our study and, therefore, lower than 1 mSv in every case matching the definition of near-to-zero fluoroscopy.\textsuperscript{28} It is important to underline that the consequent avoidance of radiation was not associated with a higher complication rate.

Limitations

To the best of our knowledge, the study evaluated the largest number of consecutive patients prospectively enrolled to undergo zero-fluoroscopy voltage-guided CTI ablation based on ME EAM so far. The compared groups were not different in relevant clinical characteristics. The sample size provides a sufficient power of over 90% for proving the main hypothesis. However, because the study is limited by the nonrandomized character of a single-center evaluation comparing a new technology with a historic population, the outcome of voltage-guiding is undergoing validation in an ongoing randomized study (Zero MAGIC, NCT04678258).

The ME technology was evaluated by intraindividual comparison with bipolar signals only within the MVG group. The results are encouraging, showing a superior visualization of conductive routes and a significant correlation with ablation requirements for ME mapping. Consequently, the question whether the use of minielectrodes provides any incremental benefit to improve the success rate of voltage-guided procedures should be evaluated further in a prospective randomized controlled trial.
The follow-up was not exactly predefined and is, therefore, limited. Although clinical follow-up was not different between the groups, targeted MVG ablation theoretically may encompass an increased risk for clinically inappropriate re-resection. A prospective study with predefined invasive re-evaluation of persistent BCB is currently evaluating this issue.

Conclusion
Substrate-guided CTI ablation, using modern AutoMap features, reduces procedure duration by obviating the need for repeat mapping and almost halves ablation time and applied energy compared with linear ablation. Individualized high-resolution mapping significantly improves identification of discrete conductive bundles. A higher number of ME-detected conducting pathways and a larger channel correlates with increased ablation requirements. Standardized subdivision of the CTI into 15 segments may support the understanding and comparability of its electroanatomy. Independent of the treatment strategy, modern EAM technology enables fast, effective, and safe ablation without the need for fluoroscopic control in the majority of cases.

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All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent
All patients provided informed consent for the intervention and data documentation.

Ethics Statement
The study was approved by the responsible ethics committee, adhered to the Declaration of Helsinki, and is registered at the German Clinical Trials Register.

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