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Journal Title: Journal of Arrhythmia
Volume: Volume 34, Number 1
Publisher: Wiley | 2018-02-01, Pages 23-29
Type of Work: Article | Final Publisher PDF
Publisher DOI: 10.1002/joa3.12006
Permanent URL: https://pid.emory.edu/ark:/25593/s9nz7

Final published version: http://dx.doi.org/10.1002/joa3.12006

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Accessed October 19, 2020 3:46 AM EDT
Use of microelectrode near-field signals to determine catheter contact

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Abstract

Background: The utility of standard distal bipolar electrograms (sEGMs) for assessing catheter-tissue contact may be obscured by the presence of far-field signals. Microelectrode electrograms (mEGMs) may overcome this limitation.

Methods: We compared 5 mEGM characteristics (amplitude, frequency content, temporal signal variability, presence of injury current, and amplitude differential between bipoles) with the sEGM for determining tissue contact in 20 patients undergoing ablation of typical atrial flutter. Visualization of catheter-tissue contact by intracardiac echocardiography (ICE) served as the gold standard for assessing contact. Correlation between electrograms and ICE-verified contact level was reported as percent concordance.

Results: Three of 5 mEGM characteristics demonstrated significantly better concordance with ICE-verified contact level than the sEGM (52% concordance with ICE): mEGM frequency content (59% concordance with ICE, \( P < .001 \) for comparison with sEGM); mEGM amplitude (concordance 59%, \( P < .001 \)); and mEGM presence of injury current (56% concordance, \( P = .001 \)). Concordance of amplitude differential between mEGM bipoles with ICE (49%) was not significantly different than the sEGM (\( P = .638 \)) whereas mEGM temporal variability (39%) was significantly worse than the sEGM. Using a median of all 5 mEGM characteristics provided additive information (concordance with ICE 64%) and was significantly better than all of the individual mEGM characteristics except frequency content (\( P = .976 \)).

Conclusion: Microelectrode EGMs (in particular frequency content, amplitude, and presence of injury current) can improve real-time assessment of catheter contact compared to the use of standard bipolar EGMs. Broader use of mEGMs may enhance ablation efficacy.

KEYWORDS

ablation, catheter contact, microelectrode electrograms
1 | INTRODUCTION

Tissue-electrode contact is a critical determinant of lesion formation and efficacy during radiofrequency ablation.\textsuperscript{1, 2} In the absence of available methods to directly assess in vivo tissue temperature and lesion formation during ablation, several surrogates of catheter contact are used clinically including assessment of local electrogram (EGM) characteristics, electrode tip temperature monitoring, impedance changes during ablation, visualization of the ablation catheter on fluoroscopy or intracardiac echocardiography (ICE), and more recently, contact force sensing. However, each of these surrogates has limitations and the inability to confirm catheter contact remains an important source of suboptimal ablation outcomes.

One of the limitations of EGM characteristics for assessing contact is that the distal bipolar electrogram recorded from an ablation catheter electrode incorporates components of both near-field and far-field signals, which may obscure local EGM characteristics most relevant for assessing contact at a site of interest. The development of an ablation catheter with miniature electrodes embedded in a radial fashion at the tip of the catheter (IntellaTip MiFi\textsuperscript{2}, Boston Scientific, Natick, MA, USA) may improve assessment of tissue-electrode contact by recording ultra-near-field EGMs and attenuating far-field components of the signal. Prior work has demonstrated significant differences in EGM characteristics between standard electrograms (sEGM) recorded from the distal bipole of the ablation catheter and microelectrode EGMs (mEGM) and has suggested a correlation between mEGM amplitude differential and contact force.\textsuperscript{3, 4} However, characteristics of mEGM signals which best correlate with tissue-electrode contact and the sensitivity of mEGM signals for determining contact have not been well characterized.

In this study, we analyzed characteristics of mEGM signals and compared them to sEGMs and ICE for determining catheter contact in a cohort of patients undergoing atrial flutter ablation.

2 | METHODS

The cohort for this analysis included patients undergoing ablation of cavotricuspid isthmus (CTI)-dependent atrial flutter. The decision to perform ablation, along with procedural details including anticoagulation management and sedation, was at the discretion of the treating physician. Two patients were enrolled in the trial but were found to have noncavotricuspid isthmus-dependent flutter during electrophysiologic study and were excluded from the analysis, resulting in a final study cohort of 20 patients.

2.1 | Compliance with ethical standards

The authors report no relevant conflict of interests. This work was supported by an investigator-initiated grant from Boston Scientific Corporation (Natick, MA, USA). This study was approved by the Emory University Institutional Review Board. All subjects provided informed consent for study participation.

2.2 | Study procedure

After confirming the diagnosis of CTI-dependent atrial flutter, an ICE catheter (ViewFlex Xtra\textsuperscript{2}, St. Jude Medical, Little Canada, MN, USA) was advanced from a femoral venous approach. The IntellaTip MiFi catheter was used to record sEGMs from the standard 8 mm distal bipole along with mEGMs from each of the 3 embedded microelectrodes (Figure 1). Intracardiac electrograms were recorded on a General Electric CardioLab analyzer (Fairfield, CT, USA) with signals at a gain of 2500 and high- and low-pass filters at 30 and 500 Hz, respectively. Under fluoroscopic and ICE guidance, the MiFi catheter was advanced sequentially to 5 locations in the right atrium: high right atrium in the region of the sinus node, low lateral right atrium along the inferior portion of the crista terminalis, cavotricuspid isthmus, coronary sinus ostium and His bundle region. At each location, sEGMs and mEGMs were recorded with the ablation catheter in full contact, intermittent contact, or poor contact with the adjacent myocardium. The ICE catheter was used to visualize the ablation catheter in contact with the adjacent myocardium throughout the cardiac cycle in order to assess the level of contact as full, intermittent, or poor. Full contact was defined as visualization of complete catheter-endocardial contact throughout the cardiac cycle during the 5-second ICE video. Intermittent contact was defined as only brief and discontinuous contact of the catheter with the endocardium or where the catheter only made contact during specific portions of the cardiac cycle (ie, systole). Poor contact was defined as failure to visualize any contact between the catheter and the endocardium such that a distinguishable space was visualized between the catheter and the endocardial surface and...
movements corresponding to the cardiac cycle could not be visualized at the catheter tip, even if an electrogram could be visualized on the catheter. Sample video clips demonstrating each of the 3 levels of contact are presented in the supplement (Videos S1–S3).

Simultaneous 5-second ICE videos and EGM recordings were taken at each of the 5 sites, at each of 3 levels of contact. After all fifteen location/contact permutations were completed, or omitted due to technical or navigational limitations, ablation of the CTI was performed using the MiFi catheter with standard technique. ICE recordings were assessed for video quality, and those considered of good or average clarity were used for assessment of contact level. Data points corresponding to videos of insufficient quality were omitted from the dataset.

### 2.3 Evaluation of electrograms

The electrograms (sEGMs and mEGMs) from each of the 5 sites at 3 levels of catheter contact were analyzed off-line in a blinded fashion by two board-certified electrophysiologists. Five mEGM characteristics were analyzed independently using a subjective 3-point scale for assessing contact level (Figure 2):

1. Electrogram amplitude: high, moderate, negligible.
2. Frequency content: high, moderate, negligible. Frequency content was defined as the number of discrete deflections present within the electrogram, with full contact defined as 3 or more discrete deflections, intermittent contact representing less than 3 discrete

![Figure 2](image)

**FIGURE 2** Examples of each of the 5 microelectrode electrogram characteristics at each of the 3 levels of tissue contact. For amplitude differential, catheter contact is judged to be good when the electrogram amplitude on 2 bipoles is significantly larger than the amplitude on the third bipoles, suggesting that one microelectrode on the opposite side of the catheter from the tissue interface is not in contact. The reference bar depicts 0.5 millivolts (mV) of amplitude.
deflections, and no contact defined as no discrete deflections (ie, continuous wave).

3. Injury current, apparent in two or more complexes: significant, moderate, absent. Injury current was presumed to be present based on local mechanical effects due to contact between the electrode-tissue interface resulting in the presence of significant deflections off the baseline at the terminal portion of the electrogram complex. Good contact was defined as significant deflection or elevation from baseline at terminal portion of electrogram on majority of complexes, intermittent complex as minimal deflections or elevation, and no contact as no identifiable deflections or elevations.

4. Temporal signal variability: stable electrogram signal, moderate temporal variability, significant temporal variability, or inadequate electrograms to assess temporal stability

5. Amplitude differential between adjacent mEGM bipoles: two bipoles with significantly greater amplitude than the third, consistent amplitude on all bipoles, insufficient amplitude to assess

For each mEGM characteristic, the first rank in each of these criteria was considered to suggest good tissue contact, the second rank was considered intermittent contact and the third rank was felt to represent poor or no tissue contact. For the sEGMs at each location, the blinded assessment was performed without knowledge of the corresponding mEGMs using only the standard electrogram appearance to rate the level of contact as full, intermittent, or poor. After blinded review of the mEGMs and sEGMs, the assessment of tissue-electrode contact based on electrogram criteria was compared to the determination of contact based on ICE as the gold standard. Assessment of ICE images was blinded to electrogram information.

The primary endpoint was correlation of each of the mEGM characteristics with ICE for determining tissue contact. Secondary endpoints included correlations between mEGMs and sEGMs for predicting tissue contact.

### TABLE 1 Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>16 (80.0)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>64.7 ± 8.9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>12 (60.0)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>4 (20.0)</td>
</tr>
<tr>
<td>History of coronary bypass grafting</td>
<td>4 (20.0)</td>
</tr>
<tr>
<td>History of percutaneous coronary intervention</td>
<td>1 (5.0)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>5 (25.0)</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>1 (5.0)</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
<td>5 (25.0)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>2 (10.0)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>4 (20.0)</td>
</tr>
<tr>
<td>End-stage renal disease on dialysis</td>
<td>1 (5.0)</td>
</tr>
<tr>
<td>History of atrial fibrillation</td>
<td>7 (35.0)</td>
</tr>
<tr>
<td>History of direct current cardioversion</td>
<td>2 (10.0)</td>
</tr>
<tr>
<td>Medications at the time of ablation</td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td>5 (25.0)</td>
</tr>
<tr>
<td>Novel oral anticoagulants</td>
<td>14 (70.0)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>4 (20.0)</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>2 (10.0)</td>
</tr>
<tr>
<td>Class Ic anti-arrhythmics</td>
<td>4 (20.0)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>1 (5.0)</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>11 (55.0)</td>
</tr>
<tr>
<td>Statins</td>
<td>8 (40.0)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>9 (45.0)</td>
</tr>
<tr>
<td>Angiotensin antagonists</td>
<td>12 (60.0)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>6 (30.0)</td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard deviation or n (%).

### TABLE 2 Interrater Agreement

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Interrater Agreement</th>
<th>kappa (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mEGM overall amplitude</td>
<td>0.76</td>
<td>0.61 (0.45, 0.77)</td>
</tr>
<tr>
<td>mEGM presence of injury current</td>
<td>0.57</td>
<td>0.27 (0.10, 0.44)</td>
</tr>
<tr>
<td>mEGM frequency content</td>
<td>0.69</td>
<td>0.53 (0.37, 0.69)</td>
</tr>
<tr>
<td>mEGM amplitude differential between adjacent bipoles</td>
<td>0.31</td>
<td>-0.05 (–0.21, 0.11)</td>
</tr>
<tr>
<td>mEGM temporal signal variability</td>
<td>0.61</td>
<td>0.40 (0.23, 0.57)</td>
</tr>
<tr>
<td>sEGM distal electrode</td>
<td>0.72</td>
<td>0.56 (0.38, 0.74)</td>
</tr>
</tbody>
</table>

Interrater agreement is determined using the percent concordance between blinded reviewers. Kappa is a measure of interrater reliability: ±1 = perfect agreement, <0 = less than chance agreement.

For each mEGM characteristic, the first rank in each of these criteria was considered to suggest good tissue contact, the second rank was considered intermittent contact and the third rank was felt to represent poor or no tissue contact. For the sEGMs at each location, the blinded assessment was performed without knowledge of the corresponding mEGMs using only the standard electrogram appearance to rate the level of contact as full, intermittent, or poor. After blinded review of the mEGMs and sEGMs, the assessment of tissue-electrode contact based on electrogram criteria was compared to the determination of contact based on ICE as the gold standard. Assessment of ICE images was blinded to electrogram information.

The primary endpoint was correlation of each of the mEGM characteristics with ICE for determining tissue contact. Secondary endpoints included correlations between mEGMs and sEGMs for predicting tissue contact.

### 2.4 Statistical analysis

To examine the agreement between mEGM characteristics and ICE-verified tissue-catheter contact, we assessed overall agreement (ie, percent concordance between predicted contact levels). In addition, we measured correlations using gamma, which is a symmetrical measure of association for ordinal variables. The estimation of gamma was obtained by number of concordances (Nc) and number of discordances (Nd), with gamma = (Nc - Nd)/(Nc + Nd). To test whether gamma was significantly different from 0, the Z test by Fisher’s transformation was used. For interobserver reliability, we reported overall agreement (percent concordance) and Cohen’s kappa coefficient (k), where 1 indicates perfect agreement and <0 indicates no agreement. P-values ≤ .05 were considered statistically significant. All analyses were performed using SAS 9.4, Cary, NC, USA.

### 3 RESULTS

Twenty patients undergoing clinically indicated ablation of CTI-dependent atrial flutter were included in this analysis. Baseline characteristics are presented in Table 1. Mean age at the time of ablation was 64.7 ± 8.9 years, 80% were male, and 35% had a concomitant history of atrial fibrillation.
Our data demonstrate that the use of microelectrode EGMs can improve real-time assessment of catheter contact compared to the use of standard bipolar EGMs. Specifically, 3 mEGM characteristics (frequency content, amplitude, and presence of injury current) demonstrated significantly better correlation with ICE-verified contact level than the sEGM and using a combination of mEGM characteristics provided additive information. Given the importance of achieving adequate catheter contact on ablation lesion formation, our data suggest that assessment of mEGMs may enhance the efficacy of ablation procedures.
Several approaches have been used to assess catheter contact during ablation procedures including electrogram characteristics, impedance and tip temperature monitoring, catheter visualization on fluoroscopy or ICE, and contact force measurement. Several different bipolar and unipolar electrogram characteristics obtained from the tip electrode on ablation catheters have been used as surrogates for assessing contact and as indicators of lesion formation, including EGM amplitude, frequency content, and electrogram stability.4,7-10 However, the correlation between sEGM characteristics and assessment of contact force based on recent studies with force-sensing catheters suggests that qualitative assessment of sEGM characteristics does not reliably predict tissue contact. In a recent analysis of left atrial sEGM characteristics, electrogram amplitude and morphology predicted contact force (CF) > 16 g with only ~60% sensitivity and specificity.7 Similar modest correlation between traditional sEGM characteristics and contact has also been demonstrated in the right atrium along the cavotricuspid isthmus.8,9 In part, the limitations of bipolar sEGMs for assessing contact may be a function of alterations in the orientation of the catheter (perpendicular vs parallel), which may significantly impact sEGM characteristics without necessarily reflecting changes in tissue contact.10 Additionally, the standard bipolar EGM represents a wider “antennae” and therefore incorporates elements of both near-field and far-field signals, which may partially obscure the utility of EGMs for predicting tissue contact.11 The use of tightly coupled microelectrode bipoles may overcome some of these limitations by minimizing the impact of far-field signals and reducing the impact of changes in catheter orientation on the ultra-near-field signals.

Our data demonstrate that mEGM frequency content, amplitude, and presence of injury current are significantly better correlated with contact level than qualitative sEGM assessment. Prior studies have demonstrated that mEGM characteristics correlate more closely than sEGMs for assessing lesion formation and efficacy of ablation in both canine models3 and in human studies of CTI ablation.11 In contrast to these prior studies, we chose to focus on assessment of mEGM characteristics to predict tissue contact at baseline (ie, pre-ablation) rather than assessing changes in mEGMs during or after ablation. Determination of contact level prior to onset of ablation may help minimize complications such as steam pops and perforation4,12 and may also optimize ablation efficacy by minimizing obscuration of local electrograms by ineffective ablation lesions delivered with inadequate contact.

We used ICE as the gold standard for determining tissue contact. Intracardiac echocardiography determined contact level has demonstrated excellent correlation with both histologic lesion formation13 and with assessments of contact force.14 Despite its demonstrated utility for improving ablation outcomes,15,16 ICE remains an imperfect surrogate for contact level. Therefore, it is conceivable that the performance of mEGMs for predicting contact level reported in our study may be an underestimate of the true utility of microelectrode signals due to the use of an imperfect reference standard. Unfortunately, platforms for simultaneously assessing contact force and mEGMs in humans are not currently available, and therefore, we are unable to correlate our results with in vivo CF measurements. However, the relationship between CF measurement and ablation outcomes is also complex, and recent randomized data suggest that CF-guided ablation may not necessarily improve ablation efficacy.17 In all likelihood, optimizing catheter contact, lesion formation, and clinical outcomes will likely require a combination of all available tools including electrogram assessment, impedance and tip temperature monitoring, visualization of the catheter, and CF measurement.

4.1 Limitations

We used semi-quantitative assessments of sEGM and mEGM characteristics, rather than determining specific thresholds (eg, amplitude cut
points) for predicting contact level. However, in clinical practice, EGMs are typically assessed in real-time using subjective metrics rather than quantitative measures, and therefore, we used similar criteria for evaluating mEGMs. Additionally, we used ICE as the reference standard for assessing the performance of mEGMs and sEGMs. Although ICE is known to be an imperfect correlate of tissue contact, in human studies where histologic assessment of lesion formation is not feasible, ICE remains a valuable tool for gauging the utility of novel tools such as mEGMs in determining catheter contact. Lastly, we do not have systematic data available on catheter orientation (perpendicular vs parallel) with regard to the electrode-tissue interface and therefore are unable to comment on the incremental utility of mEGMs vs sEGMs with different catheter orientations.

5 | CONCLUSIONS

The use of microelectrode EGMs can improve real-time assessment of catheter contact compared to the use of standard bipolar EGMs. In particular, mEGM frequency content, amplitude, and presence of injury current all demonstrated better correlation with ICE-verified contact level than sEGMs. Broader use of mEGMs may enhance ablation efficacy.

ACKNOWLEDGEMENTS

This work was supported by an investigator-initiated grant from Boston Scientific Corporation (Natick, MA).

CONFLICTS OF INTEREST

Authors declare no Conflict of Interests for this article.

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REFERENCES


SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

How to cite this article: Levy MR, Merchant FM, Langberg JJ, Delurgio DB. Use of microelectrode near-field signals to determine catheter contact. J Arrhythmia. 2018;34:23–29. https://doi.org/10.1002/joa3.12006