


ORIGINAL ARTICLE

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.^{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[®], 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.^{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[®], 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

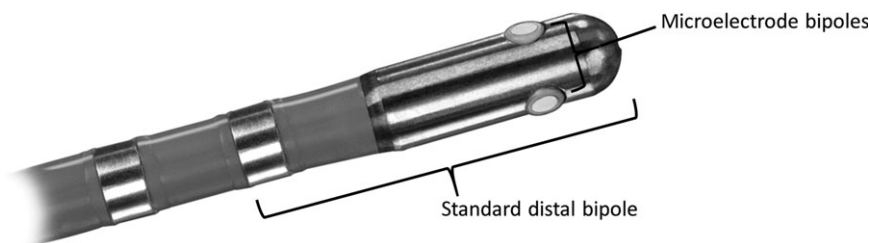


FIGURE 1 Image of the ablation catheter with microelectrodes embedded in a radial fashion at the tip (IntellaTip MiFi[®], Boston Scientific, Natick, MA). Center-to-center distance between the embedded microelectrodes is 2.5 mm used to generate 3 ultra-near-field-sensing bipoles. The standard distal bipole is also highlighted. Figure adapted with permission from Boston Scientific Corporation

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 offline 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

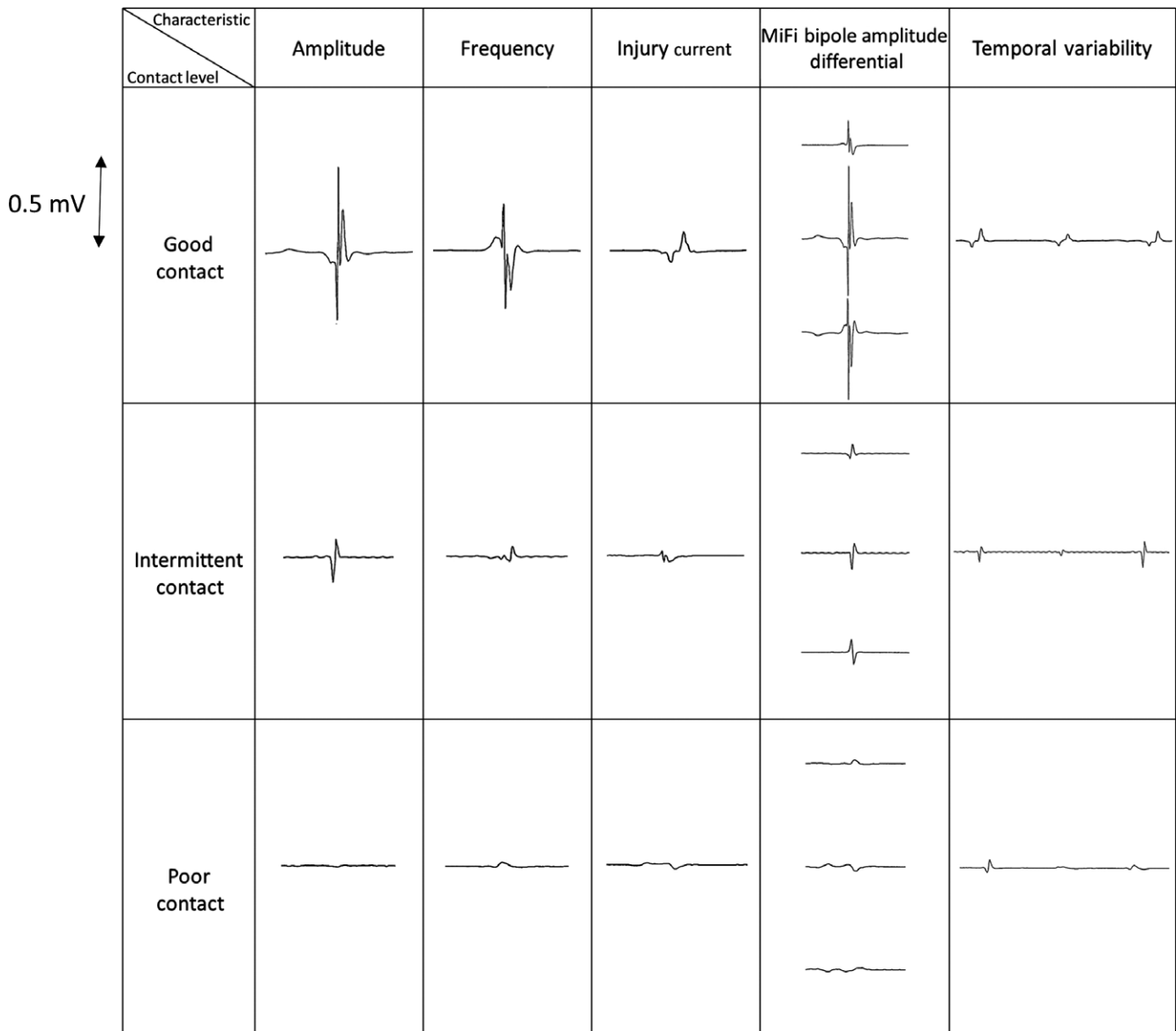


FIGURE 2 Examples of each of the 5 microelectrode electrogram characteristics at each of the 3 levels of tissue contact. For amplitude differential, catheter contact is judged to be good when the electrogram amplitude on 2 bipoles is significantly larger than the amplitude on the third bipole, suggesting 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).

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

TABLE 1 Baseline characteristics

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

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

TABLE 2 Interrater Agreement

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

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.

mEGM, microelectrode electrogram; sEGM, standard bipolar electrogram.

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 $\text{gamma} = (Nc - Nd)/(Nc + Nd)$.⁵ 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 (κ), where 1 indicates perfect agreement and <0 indicates no agreement.⁶ 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.

TABLE 3 Electrogram performance for predicting contact

Characteristic	Correlation with ICE Determined Contact Level			Comparison with sEGM distal electrode	Comparison with median of 5 mEGM characteristics	Comparison with median of 3 mEGM characteristics ^a
	Overall Agreement	Gamma (95% CI)	P-value	P-value	P-value	P-value
mEGM overall amplitude	0.59	0.71 (0.61, 0.80)	<.0001	.0007	.0385	.0801
mEGM presence of injury current	0.56	0.70 (0.60, 0.80)	<.0001	.001	.0285	.0615
mEGM frequency content	0.59	0.78 (0.71, 0.85)	<.0001	<.0001	.9761	.7263
mEGM amplitude differential between adjacent bipoles	0.49	0.55 (0.43, 0.67)	<.0001	.6384	<.0001	<.0001
mEGM temporal signal variability	0.39	−0.03 (−0.18, 0.12)	.8108	<.0001	<.0001	<.0001
sEGM distal electrode	0.52	0.52 (0.37, 0.67)	<.0001	N/A	<.0001	<.0001
Median of all 5 mEGM characteristics	0.64	0.78 (0.70, 0.86)	<.0001	<.0001	N/A	.749
Median of 3 mEGM characteristics*	0.62	0.77 (0.69, 0.85)	<.0001	<.0001	.749	N/A

ICE, intracardiac echocardiography; mEGM, microelectrode electrogram; sEGM, standard bipolar electrogram.

^aMedian of 3 mEGM characteristics includes: overall amplitude, injury current, and frequency content.

Of a possible 300 sets of EGM and ICE data points (20 patients × 5 locations in the RA per patient × 3 levels of contact at each location), 17% of data points were felt to be not analyzable due to inadequate ICE image quality to assess catheter contact level or technical/navigational limitations which prevented collection of adequate EGMs at a particular site. This resulted in a total of 244 sets of EGM and ICE images which were included in the final analysis.

Interobserver agreement between the blinded reviewers for determining contact level based on electrogram characteristics is presented in Table 2. Concordance between reviewers was highest for mEGM amplitude (0.76), whereas concordance was lowest for the amplitude differential between mEGM bipoles with a kappa statistic less than 0, suggesting no better than chance agreement. Concordance levels showed moderate agreement between reviewers for mEGM frequency content, temporal signal variability, and presence of injury current. Interobserver concordance for determining contact level when assessing the standard distal bipolar electrogram was also relatively good (0.72). The interobserver reproducibility for the sEGM was not quite as good as the mEGM amplitude, but better than other mEGM characteristics.

The level of concordance between mEGM characteristics to assess tissue contact and ICE-verified contact level is presented in Table 3. Intensity of mEGM frequency content correlated most strongly with ICE-verified contact level (59% concordance, gamma = 0.78), with mEGM amplitude (59% concordance, gamma = 0.71) and presence of mEGM injury current (56%, gamma = 0.70) also demonstrating moderately good correlations with ICE-verified contact level. Amplitude differential between mEGM bipoles demonstrated a weaker but still positive correlation with ICE (49%, gamma = 0.55) whereas concordance between mEGM temporal signal variability and ICE had poor correlation (39%, gamma = -0.03). The standard bipolar EGM also demonstrated modest concordance with ICE (53%, gamma = 0.58). Three of the mEGM characteristics (amplitude, frequency content, and presence of injury current) demonstrated

significantly better concordance with ICE than the sEGM, whereas mEGM temporal signal variability was significantly worse than the sEGM. Figure 3 shows simultaneous recordings from the sEGM and mEGMs in good contact and poor contact, highlighting the manner in which the mEGM accentuates local near-field electrogram characteristics.

In addition to the 5 discrete mEGM characteristics and the sEGM for assessing contact levels compared to ICE, we also assessed combinations of electrograms to see whether multiple characteristics provided better correlation with ICE than individual criteria. Using a median of contact levels assessed by all 5 mEGM characteristics, the level of correlation with ICE improved to 64% (gamma = 0.78), which was significantly better than all of the individual mEGM characteristic except for mEGM frequency content. A median of the 3 best mEGM characteristics (amplitude, presence of injury current, and frequency content) performed almost as well (concordance with ICE 0.62, gamma = 0.77) as using all 5 mEGM characteristics ($P = .749$ for comparison between using a median of 3 vs 5 mEGM characteristics). However, the median of 3 mEGM characteristics was not significantly better than using either mEGM amplitude, presence of injury current, or frequency content in isolation.

4 | DISCUSSION

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.

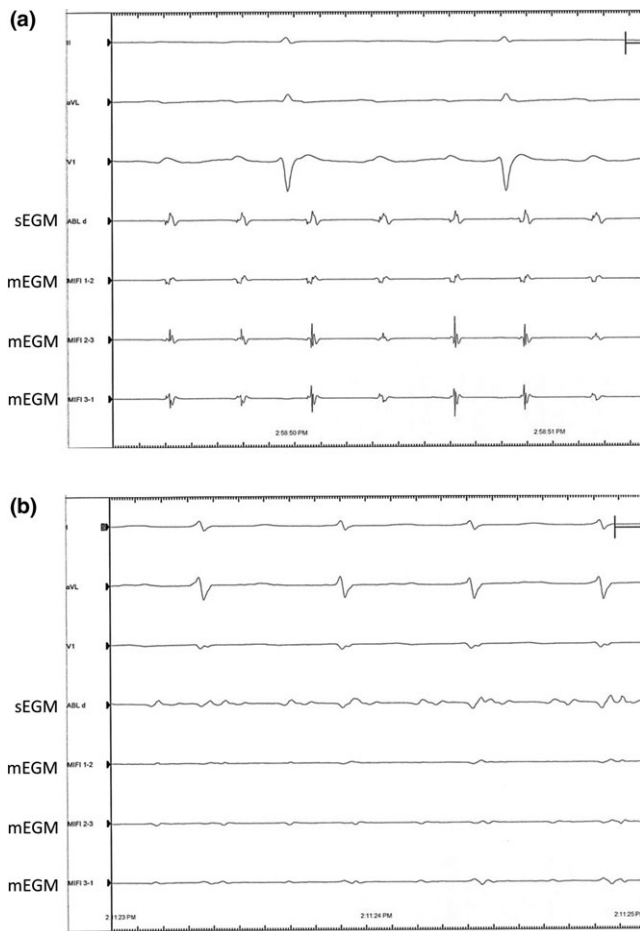


FIGURE 3 Simultaneous demonstration of electrograms from the standard distal bipole (sEGM) and microelectrodes (mEGM) with good contact (panel A) and poor contact (panel B). In both examples, the mEGMs provide an enhanced assessment of the near-field characteristics. In panel A, the mEGMs (in particular MiFi 2-3 and 3-1) demonstrate greater frequency content as evidenced by electrograms with multiple discrete deflections, higher EGM amplitude than the distal bipole and the presence of amplitude differential between adjacent bipoles (MiFi 2-3 and 3-1 showing greater amplitude than MiFi 1-2). In contrast, in panel B, although atrial electrograms can be discerned on the sEGM, the mEGMs show very little near-field activity and do not demonstrate any of the characteristics of good contact

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 perforation^{4,12} 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.

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CONFLICTS OF INTEREST

Authors declare no Conflict of Interests for this article.

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SUPPORTING INFORMATION

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

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