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Confirmation of Pulmonary Vein Isolation with High-Density Mapping: Comparison to Traditional Workflows

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Abstract

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) ablation. Yet tools and techniques used for confirmation of PVI vary greatly, and it is unclear whether the use of any particular combination of tools and techniques provides greater sensitivity for identifying gaps periprocedurally. It has been suggested that the use of a high-density mapping catheter, which enables simultaneous recording of adjacent bipolar EGMs in two directions, may provide improved sensitivity for gap identification. Anonymized, acute procedural data was prospectively collected in AF ablation cases utilizing various workflows for confirmation of PVI. Post-hoc analysis was performed to evaluate the incidence of gaps detected by different diagnostic catheter technologies, including a high-density mapping catheter and circular mapping catheters (CMCs), and common techniques such as pacing the ablation lines. A total of 139 cases were included across three subgroup analyses: 99 cases were included in an indirect comparison of three mapping catheter technologies, revealing gaps in 36.7%, 38.9%, and 81.8% of cases utilizing a 10-pole CMC, 20-pole CMC, and a high-density mapping catheter, respectively; a direct comparison of diagnostic catheter technologies in 18 cryoballoon ablation cases revealed residual gaps in 22.2% of patients identified by high-density mapping which were missed previously with the use of a 3.3F CMC; in 22 cases utilizing a technique of pacing the ablation lines, high-density mapping identified residual gaps in 68.2% of patients. This proof of concept analysis demonstrated that the use of a high-density catheter which records orthogonal bipoles simultaneously, appears to improve acute detection of gaps in PVI lines relative to other commonly utilized techniques and technologies. The long-term impact of ablating these concealed gaps remains unclear. Further study, including direct comparison of diagnostic catheter technologies in a randomized setting with long-term followup, is warranted.

Key Words

Atrial Fibrillation, Pulmonary vein isolation (PVI), High density mapping.

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Introduction

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) ablation, but the precise methodology used for confirming this endpoint varies greatly across operators. Circular mapping catheters are the most commonly used tool for confirming PVI, and bidirectional block is widely regarded as the optimal

endpoint. Assessment of entrance block is relatively simple, but confirmation of exit block presents technical challenges, requiring confirmation of local capture within the pulmonary vein while avoiding locations which result in far-field superior vena cava or left atrial appendage capture[1-3]. These technical challenges may make it difficult to obtain objective confirmation of bidirectional block in all patients.

In an effort to augment the assessment of durable PVI, some have advocated for protocols incorporating waiting periods, adenosine, and/or isoproterenol. While dormant conduction can be unmasked using these techniques, randomized trials have provided conflicting results in terms of long-term efficacy[4-6]. Additional techniques have been proposed, including pacing the ablation lines around the pulmonary veins to confirm loss of pace capture. Results of these studies appear promising, but procedural efficiency may be sacrificed[7, 8]. Cryoballoon ablation was later introduced as a simplified method for creating continuous lesions. This methodology has its own limitations however, such as the uniform delivery cryoablation therapy around segments of the pulmonary veins which have varying myocardial thickness. Confirmation of PVI in these cases is commonly achieved using a circular mapping catheter which is subject to the same limitations previously identified.

A limitation common to all bipolar electrogram recordings is directional sensitivity: larger amplitudes are recorded when the wavefront is propagating parallel to the electrode pair compared to when propagation is perpendicular to the electrode pair. This limitation of standard bipoles may be important when assessing pulmonary vein isolation, considering that previous study has demonstrated longitudinal, circumferential, and oblique myocardial fiber entry into the pulmonary veins[10]. Standard diagnostic catheters often incorporate bipoles arranged in a single plane, which could fail to identify activation entering the veins at an angle oblique or perpendicular to those bipoles. The Advisor™ HD Grid Mapping Catheter (HD Grid) (Abbott, Minneapolis, MN) is a high-density mapping catheter which uniquely enables sampling of bipolar electrograms in two directions, simultaneously (Figure 1). It has been suggested that this may enable detection of local electrograms which could be missed by other technologies[11]. We sought to collate multicenter data enabling a comparative assessment of sensitivity to PVI gap detection between this high-density mapping catheter and other diagnostic catheter technologies.

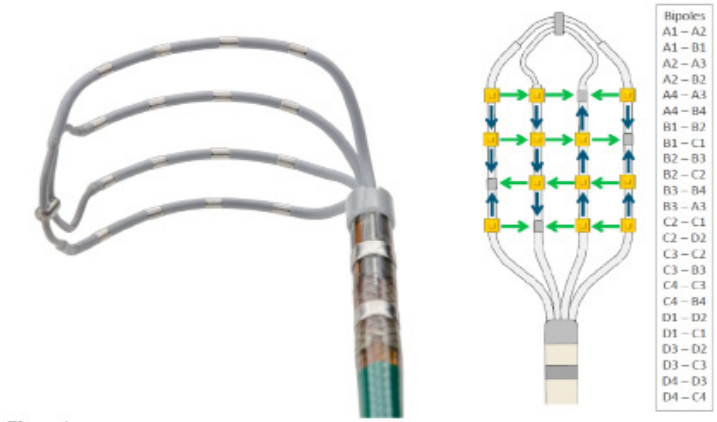

Figure 1: Advisor HD Grid Mapping Catheter, Sensor Enabled (left) and an example HD Wave Solution configuration which records bipolar electrograms in two directions, simultaneously (right).

Table 1: Waiting period utilization and duration distribution across the three groups included in the circular mapping catheter analysis. While 12 out of the 30 (40%) cases in the CMC10 group reported utilization of a 30 minute waiting period, 35 out of 36 (97.2%) cases in CMC 20 group and 29 out of 33 (87.9%) cases in the HD Grid group did not utilize a waiting period as part of the PVI confirmation method.

Waiting Period Duration (min)	CMC10 (n = 30)	CMC20 (n = 36)	HD Grid (n = 33)
0 (no waiting period)	3.3% (1/30)	97.2% (35/36)	87.9% (29/33)
5	26.7% (8/30)	0.0% (0/36)	3.0% (1/33)
15	16.7% (5/30)	0.0% (0/36)	6.1% (2/33)
20	6.7% (2/30)	2.8% (1/36)	0.0% (0/33)
30	40.0% (12/30)	0.0% (0/36)	3.0% (1/33)
NR	6.7% (2/30)	0.0% (0/36)	0.0% (0/33)

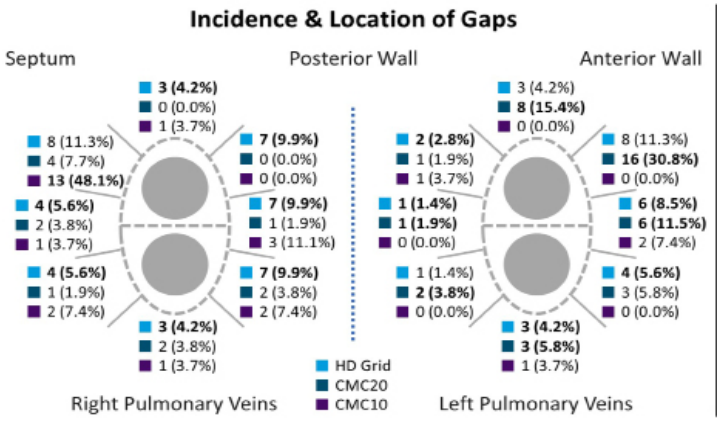

Figure 2: Incidence and location of gaps identified by three diagnostic catheter technologies (percentage of total gaps detected by each technology). HD Grid identified significantly more gaps than the other two technologies (p = 0.015), identifying an average of 49.0% and 139.1% more gaps per patient than CMC20 and CMC10, respectively (HD Grid: 2.15/patient; CMC20: 1.44/patient; CMC10: 0.9/patient).

Methods

Data Collection

Anonymized, acute procedural data were prospectively collected in atrial fibrillation ablation cases performed from May – October 2019, at 24 centers in the United States and Europe. All procedures were conducted per the operator's standard of care. Data was self-reported using a standardized case report form.

Analysis

The primary outcome of each post-hoc analysis was the incidence and location of gaps detected by various pulmonary vein isolation confirmation techniques and diagnostic catheter technologies. Criteria for confirming presence of a gap were left to the discresion of the operator. Included was an indirect comparison of HD Grid to

Table 2: Ablation catheter utilization across the three groups included in the circular mapping catheter analysis. Contact force-sensing catheters were used in all but 1 case.

Ablation Catheter	CMC10	CMC20	HD Grid
TactiCath SE	40.0% (12/30)	100.0% (36/36)	100.0% (33/33)
TactiCath Quartz	56.7% (17/30)	0.0% (0/36)	0.0% (0/33)
Other	3.3% (1/30)	0.0% (0/36)	0.0% (0/33)

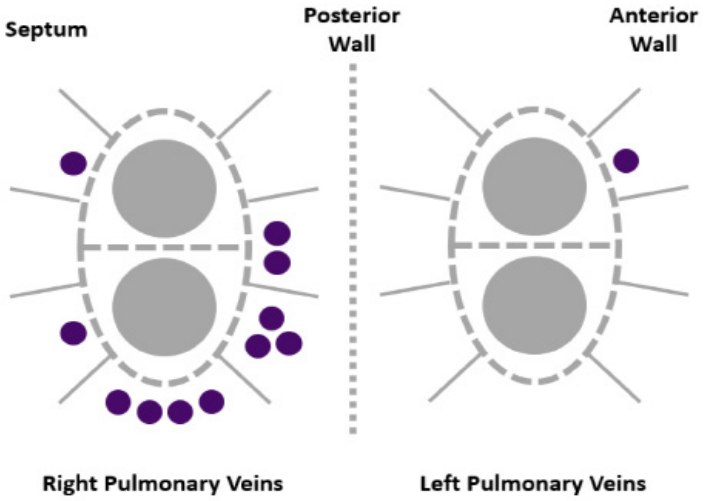

Figure 3: Incidence and location of residual gaps (across all cryoablation patients in which gaps were recorded) identified by Advisor HD Grid, which were not identified by the Achieve. The Achieve catheter was used to confirm isolation after cryoablation followed by the use of the HD Grid to reconfirm isolation. The HD Grid identified a total of 12 gaps in 4 (22.2%) patients, which were missed by the Achieve catheter. All except for one gap were in the right pulmonary veins. The majority of the gaps identified in the right pulmonary veins were located in the inferior regions.

circular mapping catheters (Circular Mapping Catheters), a direct comparison of HD Grid to the Achieve maping catheter (Medtronic, Minneapolis, MN) post-cryoballoon ablation (Cryoballoon Ablation), and a direct comparison of HD Grid to a technique of pacing the ablation lines (Loss of Pace Capture). The EnSite Precision Cardiac Mapping System (Abbott, Minneapolis, MN) was utilized in cases which included 3D mapping. Cases meeting the criteria for each group were selected for inclusion.

Circular Mapping Catheters

De novo atrial fibrillation radiofrequency (RF) ablation procedures utilizing a 10-pole circular mapping catheter (CMC10), 20-pole circular mapping catheter (CMC20), and HD Grid were selected for analysis. PVI confirmation techniques, along with the incidence and location of gaps, were recorded. The proportion of patients in which each technology identified a gap was quantified along with the average number of gaps identified per patient.

Cryoballoon Ablation

Atrial fibrillation cryoablation procedures in which isolation was confirmed with the Achieve mapping catheter followed by secondary confirmation with the HD Grid, were selected for analysis. The incidence and location of residual gaps identified by the HD Grid was quantified.

Table 3: Ablation power utilization across the three groups included in the circular mapping catheter analysis.

Ablation Power	CMC10	CMC20	HD Grid
Anterior/Roof Pulmonary Vein Segments			
30W	73.3% (22/30)	0.0% (0/36)	12.1% (4/33)
35W	10.0% (3/30)	11.1% (4/36)	21.2% (7/33)
40W	0.0% (0/30)	30.6% (11/36)	3.0% (1/33)
45W	0.0% (0/30)	16.7% (6/36)	54.5% (18/33)
50W	16.7% (5/30)	41.7% (15/36)	9.1% (3/33)
Posterior/Inferior Pulmonary Vein Segments			
25W	50.0% (15/30)	0.0% (0/36)	6.1% (2/33)
30W	33.3% (10/30)	11.1% (4/36)	27.3% (9/33)
35W	0.0% (0/30)	30.6% (11/36)	21.2% (7/33)
45W	0.0% (0/30)	16.7% (6/36)	36.4% (12/33)
50W	16.7% (5/30)	41.7% (15/36)	9.1% (3/33)

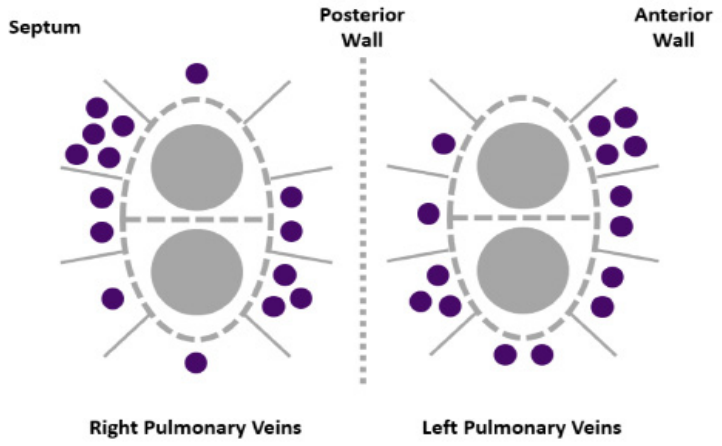

Figure 4: Incidence and location of residual gaps (across all pacing-cohort patients in which gaps were recorded) identified by Advisor HD Grid, which were not identified by pacing the ablation line. PVI was confirmed by pacing along the ablation line with subsequent PVI assessment using HD Grid and the HD Wave configuration. The HD Grid identified a total of 30 gaps in 15 (68.2%) patients, which were initially missed by pacing along the ablation lines.

Loss of Pace Capture

Atrial fibrillation RF ablation procedures in which isolation was confirmed using a technique of pacing the ablation lines followed by secondary confirmation with the HD Grid, were selected for analysis. The incidence and location of residual gaps identified by the HD Grid was quantified.

Statistical Analysis

Post-hoc statistical analysis was performed. Categorical variables are expressed as counts and percentages. Difference between the groups were tested for statistical significance by one-way ANOVA or two sample t-test. A two tailed p value less than 0.05 was considered statistically significant.

Results

Data was collected in a total of 198 atrial fibrillation ablation cases, 50.5% of which were contributed by operators in Europe. A total of 139 cases met the inclusion criteria for one of the three analyses.

Circular Mapping Catheters

A total of 99 cases met the inclusion criteria. PVI was confirmed via entrance and/or exit block in all cases. CMC10 was utilized in 30 cases (66.7% PAF; 33.3% PersAF), CMC20 in 36 (38.9% PAF; 61.1% PersAF), and HD Grid in 33 (69.7% PAF; 27.3% PersAF; 3.0% LsPersAF). Average age was 62.8 ± 12.1, 68.3 ± 10.9, and 65.1 ± 8.7 years in the CMC10, CMC20, and HD Grid groups, respectively. Use of adenosine varied across groups (CMC10: 6.7%; CMC20: 86.1%; HD Grid: 41.7%, $p<0.05$), as did application of a waiting period ranging from 5-30 minutes (CMC10: 96.7%; CMC20: 2.8%; HD Grid: 11.1%, $p<0.05$); Table 1 shows the distribution of waiting period duration across the three groups. The ablation catheters and power settings used in each group are identified in Tables 2 and 3. Gaps were identified in in 36.7%, 38.9%, and 81.8% of cases using CMC10, CMC20, and HD Grid, respectively. HD Grid identified significantly more gaps than the other two technologies ($p = 0.015$), identifying an average of 49.0% and 139.1% more gaps per patient than CMC20 and CMC10, respectively (Average number of gaps per patient - HD Grid: 2.15/patient; CMC20: 1.44/patient; CMC10: 0.9/patient). The location and incidence of gaps identified by each technology is shown in Figure 2.

Cryoballoon Ablation

A total of 18 cases met the inclusion criteria. De novo and repeat ablations represented 77.8% and 22.2% of cases, respectively. 3D mapping was employed in 94.4% of cases. A left common pulmonary vein was present and ablated in 11.1% (2/18). The 28mm cryoballoon was utilized in all cases, with a single case using both a 23mm and 28mm cryoballoon. The 3.3F CMC was used to confirm isolation in all cases using a variety of techniques: voltage mapping (72.2%), exit block (44.4%), entrance block (38.9%), propagation mapping (5.6%), and activation mapping (5.6%); note: total exceeds 100% as more than one technique may be employed in a single case. The HD Grid identified a total of 12 gaps in 4 (22.2%) patients, which were missed by the 3.3F CMC. All except for one gap were in the right pulmonary veins. The majority of the gaps identified in the right pulmonary veins were located in the inferior regions (Figure 3). No adenosine or isoproterenol use was documented in any case.

Loss of Pace Capture

A total of 22 cases met the inclusion criteria. De novo and repeat ablations represented 72.7% and 22.7% of cases, respectively (4.5% not reported). PVI was confirmed by pacing along the ablation line with an average output of 8.8 ± 1.9mA and pulse width of 2.2 ± 0.7ms (10mA at 2ms was utilized in 59.1%). Subsequent PVI assessment was performed with HD Grid. PVI confirmation techniques with HD Grid included exit block confirmation (90.9%), voltage mapping (59.1%), loss of pace capture along ablation lines (40.9%), entrance block confirmation (18.2%), and activation mapping (4.5%); note: total exceeds 100% as more than one technique may be employed in a single case. The HD Grid identified a total of 30 gaps in 15 (68.2%) patients, which were initially missed by pacing along the ablation lines. Gaps were quite evenly distributed around the left and right pulmonary veins (Figure 4). No adenosine or isoproterenol use was documented in any case.

Discussion

Acute procedural endpoints which provide objective and consistent assessment of durable pulmonary vein isolation have been elusive. This could be the result of insufficient sensitivity of commonly used diagnostic tools and techniques for the acute detection of gaps in these lesion sets. The results presented in this proof of concept analysis suggest that sensitivity for gap detection is indeed highly variable when comparing multiple common workflows for PVI confirmation.

One early study compared the resolution of PV potentials recorded by a 20-pole CMC (1mm bipole spacing) to those recorded by the same catheter with bipoles configured to mimic a 10-pole CMC (6mm bipole spacing)[12]. The 20-pole configuration recorded PV potentials with higher amplitude and greater detail as demonstrated by an increase in observed fractionation. Improved EGM resolution has also been identified in studies evaluating high-density mapping catheters[13-15]. Considering these previous findings, it is no surprise that more gaps were identified in cases utilizing catheters with increasing electrode number and decreasing bipole spacing. Interestingly, this trend existed despite scarce application of waiting periods in the CMC20 and HD Grid groups while waiting periods were applied quite uniformly in the CMC10 group, with 70.0% applying a waiting period of 15 minutes or more. Increasing waiting time should improve detection of gaps yet in this case, it appears the impact of diagnostic catheter technology outweighed the potential impact of waiting periods.

Perhaps less apparent is the cause of the difference in gap incidence observed with HD Grid and 20-pole CMCs, which have a similar number of electrodes and bipole spacing (Figure 2). One explanation could be the effect of wavefront direction on the amplitude of bipolar EGMs, with larger amplitudes recorded when the wavefront is propagating parallel to the electrode pair compared to when propagation is perpendicular to the electrode pair. This directional sensitivity has been well documented clinically[11, 13, 16-21]. By recording bipolar electrograms in two directions simultaneously, HD Grid could enable better discrimination of local electrograms suggesting the presence of a gap. Another possible explanation could be the relative location at which electrograms are sampled. Circular mapping catheters tend to be positioned more distally in the vein, potentially missing shorter fibers in the antral portion of the vein which may be identified when the HD Grid is used in a manner that samples closer to the ablation line. While the underlying mechanism is not completely understood, the indirect comparison presented here demonstrates a strong trend suggestive of improved gap detection with the HD Grid. Results from direct comparison of HD Grid to the Achieve mapping catheter post-cryoablation appear to validate the hypothesis that HD Grid improves gap detection. Residual gaps were identified in approximately 20% of patients with the HD Grid after isolation had been confirmed using the Achieve, with the majority of the gaps identified around the right inferior pulmonary veins (Figure 3).

A technique of pacing the ablation lines around the pulmonary veins, confirming loss of pace capture, has also been suggested to improve PVI durability. Previous trials have demonstrated PVI rates, as confirmed by electrograms on the circular mapping catheter, of 95-97% following loss of pace capture along the ablation lines[7, 8]. Further, randomized trials have demonstrated significantly improved long-term outcomes when this technique is used as an adjunct to bidirectional block confirmed by a circular mapping catheter[8, 22]. Our results build on this work by establishing a direct comparison to a contemporary, high-density mapping catheter. While the sample size is small, the rate of residual gaps detected by HD Grid after confirming isolation by pacing suggests that this technique, used in isolation, may not be sufficient for confirmation of PVI (Figure 4).

Limitations across all of these analyses include the relatively small sample sizes and observational nature of the data collection (i.e., ablation technique, PVI confirmation technique, etc. likely varied between operators and there was no minimum operator experience criteria for participation). Criteria for confirmation of gaps were not standardized, instead being left to the discretion of the operator. Considering specifically the indirect comparison (Circular Mapping Catheters), results could be impacted by factors such as the operator, ablation technique, PVI confirmation technique, patient demographics (e.g., left atrial diameter or CHA_2DS_2-VASc), etc. It must also be noted that direct comparisons consistently assessed PVI with the HD Grid after confirming isolation with other techniques.

Despite these limitations, the results suggest that as new diagnostic catheter technologies are introduced, it would be prudent to reassess even routine aspects of atrial fibrillation ablation, such as confirmation of PVI. Additional study is warranted, and randomized trials will be necessary to validate the clinical value provided by these technologies.

Conclusion

Diagnostic catheter technology continues to evolve rapidly, but studies investigating the impact that these technologies may have in assessing durable PVI remain scarce. Use of the HD Grid catheter appears to improve acute detection of gaps in PVI lines relative to other commonly utilized technologies. The impact that ablation of these concealed gaps may have on long-term clinical outcomes remains unknown. Further study, including direct comparison of diagnostic catheter technologies in a randomized setting, is warranted.

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