

Additional Diagnostic value of Mini Electrodes in an 8-mm Tip in Cavotricuspid Isthmus Ablation

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Abstract

Background: Eight-mm ablation catheters are widely used in cavotricuspid isthmus ablation (CTI) for treatment of right sided atrial flutter. However a high success rate, these large ablation tips comes with disadvantage of lower resolution of fractionated signals.

Purpose: The aim of this study was to evaluate the additional diagnostic value of the electrograms recorded from mini electrodes (MEs) in an 8-mm ablation catheter tip during CTI.

Methods: CTI-ablation procedures were compared retrospectively in two groups, namely, group A: the Abbott Safire 8-mm tip with a 3D mapping system (n =37) and group B: the Boston Scientific MiFi IntellaTip XP 8-mm tip without a 3D mapping system (n=13). We analyzed acute procedural success, ablation characteristics and recurrence rate at one-year follow-up. Electrograms from MEs were analyzed right before the onset of the critical ablation application that resulted in acute CTI-block. We determined whether these ME electrograms had additional diagnostic value in addition to of the 8-mm tip derived electrogram.

Results: At the onset of the critical ablation application, the MEs had an important additional value in 3 out of 13 cases as local signals were sensed on the MEs that were not recorded by the 8-mm tip electrode. In 2 cases the ME did not show local electrograms although the ablation was still effective. Acute procedural and long-term success were observed in all patients. No differences were found in time to bidirectional block, procedure time or fluoroscopic exposure.

Conclusions: Our data show that signals recorded from the MEs had additional diagnostic value, but only in a small percentage of the patients. We did not observe, although omitting 3D-mapping in the ME group, any difference between groups with regard to procedural or ablation characteristics during CTI-ablation.

Introduction

Right isthmus-dependent atrial flutter (AFL) is one of the most common supra-ventricular arrhythmias. The activation front during tachycardia travels through a macro-reentrant circuit in the right atrium, encompassing the isthmus located between the tricuspid annulus and inferior vena cava (cavotricuspid isthmus, CTI)^[1,2]. Consequently, typical counter-clockwise AFL is characterized by a negative p-wave with a saw-tooth pattern in the inferior leads of the 12-lead ECG^[3]. Due to the stability of the circuit, rate control can be challenging. Rhythm control strategies consist of pharmacological treatment, electrocardioversion or radiofrequency (RF) ablation^[4].

CTI-ablation is widely used and effective at restoring and maintaining sinus rhythm. The first reports describe the use of a 4-mm non-irrigated catheter to create an ablation line of conduction block along the CTI^[1]. Anatomical variance among CTI patients

in combination with a small ablation electrode size can cause lack of convective cooling. This may result in a temperature rise of the ablation tip and decreased power delivery. This, in turn, will result in a smaller lesion size and an increased risk of steam-pops. By using a larger ablation electrode size, more electrode surface is available for convective cooling, resulting in increased power delivery and greater lesion size^[5-8]. Indeed, several investigators have described the superiority of an 8-mm ablation catheter compared to a 4-mm non-irrigated ablation catheter^[9-11]. However, this advantage comes at the cost of lower resolution of local fractionated electrograms. To overcome this issue, a new 8-mm tip ablation catheter was recently developed, equipped with mini electrodes (MEs) to optimize sensing of local electrograms. In this ablation catheter, three 1-mm electrodes are located within 2-mm of the ablation catheter tip with a 2,5-mm spacing (Figure 1). A small study of Iwasawa et al^[12], and a case series of Tzeis et al^[13], showed conflicting outcomes in efficacy using MEs in an 8-mm catheter. Furthermore, it has not been established in for what percentage of patients MEs detect local electrograms, when electrograms on the conventional bipolar electrodes are absent. Therefore, the question remains as to whether the use of MEs results in increased procedural efficacy, and whether the use of MEs allows a 3D navigation system to be omitted.

Key Words

Catheter Ablation, Atrial Flutter, Cavotricuspid Isthmus, Mini Electrodes

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Methods

Population and study design

Fifty consecutive patients who underwent a CTI-ablation between 2013 and 2016 in the OLVG hospital in Amsterdam, the Netherlands were included in this analysis. The local ethics committee approved this retrospective study and issued a waiver for informed consent.

We compared two groups: group A consisted of patients undergoing CTI-ablation using the Safire F 8-mm (Abbott, Abbott Park, IL, USA) ablation catheter in combination with a 3D mapping system (n = 37); group B consisted of patients undergoing CTI-ablation using the MiFi IntellaTip XP 8-mm (Boston Scientific, Boston, MA, USA) ablation catheter without a 3D mapping system to attain an electrogram based ablation (n = 13). Patients with a prior CTI-ablation or atrial tachycardias not dependent on the CTI were excluded. Atrial size was qualitatively assessed by transthoracic echocardiogram. Ablation was performed either by using a point-by-point or focal application of about 30 seconds before dragging forward, with a maximum application duration of 240 seconds. The RF strategy was chosen as per the operator preference. The final RF application that resulted in CTI-block was defined as the critical application. We compared the presence of interpretable intracardiac electrograms from the MEs to those intracardiac electrograms recorded from the conventional electrodes at the onset of the critical application. An interpretable cardiac recording (non-zero) was defined as a peak-peak amplitude of the bipolar electrogram >0.2mV at the steepest dv/dt for the conventional 8-mm tip and >0.1mV for recordings retrieved from the MEs. Electrograms with lower amplitudes were supposed to represent a zero potential. In both groups we recorded procedure time, time to bidirectional block, fluoroscopic exposure, total ablation time, total number of ablation applications and the need to use a steerable sheath.

Procedural characteristics

All procedures were performed with an opioid analgesic (fentanyl) and without sedation. The femoral vein was punctured for access. A duo decapolar diagnostic catheter was placed in the right atrium around the tricuspid annulus; a quadripolar diagnostic catheter was placed in the coronary sinus. Surface ECG and intracardiac recordings were acquired with a Bard EP recording system (Boston Scientific, Boston, MA, USA). Filter settings on the ablation channel were similar for both conventional 8-mm and ME recordings. We used 30-250Hz band-pass filter and a notch filter. The Ensite 3D mapping system (Abbott, Abbott Park, IL, USA) was only used in group A. RF-energy was delivered using IBI-1500T11 (Abbott, Abbott Park, IL, USA); ablation generator settings were 70W and 55 degrees Celsius. Bidirectional block was assessed with bidirectional differential pacing manoeuvres^[14] and by measuring the width of the local double potentials. Procedural success was achieved when bidirectional block was still present after a waiting period of 20 minutes after the last RF application.

Follow-up

Follow-up data was collected from electronic patient records at one-year and by investigating all rhythm recordings performed by the

referring hospitals. Recurrence was defined as registration of AFL on a 12-channel ECG, regular atrial tachycardia with a cycle length between 200-260ms in a cardiac implantable electronic device, or Holter registration. Recurrence of symptoms without documentation of arrhythmias was documented as well.

Statistical Analysis

Statistical package for social science (SPSS) was used for statistical analyzes (SPSS Inc., Chicago, IL, USA). Normally distributed continuous variables are presented with a mean and a standard deviation, non-normally distributed with a median and an interquartile range, categorical variables in numbers and percentages. The parametric independent T-test and non-parametric Mann-Whitney U-test were used for statistical analysis of continuous variables, while X² and Fisher's exact test were used to compare numbers between groups.

Results

We included 50 patients with a typical AFL (n=37 in group A vs. n=13 in group B) of whom 84% were male. Mean age was 63.3 ± 8.6 years. Right atrium dilatation was present in 41.5% of the patients (n=11 vs. n=6 patients p=0.678). Counter-clockwise activation was observed in 46 patients (n=35 vs. n=11 p=0.069) whereas clockwise activation was also observed in 7 of these patients (n=5 in group A and n=2 in group B). Baseline patient characteristics are summarized in [Table 1]. Twenty-one patients (56.8%) in group A and 5 patients (38.5%) in group B had a history of atrial fibrillation (p=0.265). In group A 3 patients (8.1%) used flecainide compared to 5 (38.5%) in group B (p=0.010). [Figure 1A] shows a graphic of the localization of MEs on the ablation catheter and [Figure 1B] shows the conventional ablation catheter.

CTI ablation was associated with acute procedural success of 100% in both groups. There was no difference in any of the

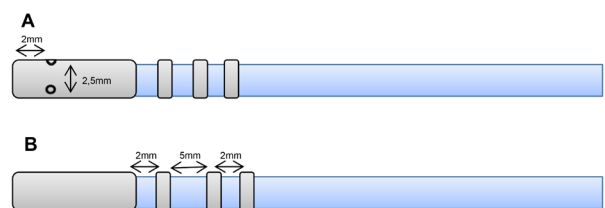


Figure 1: 8-mm ablation catheter with 1-mm mini electrodes within a 2-mm distance from the ablation tip and a 2,5-mm spacing. B, conventional 8-mm ablation catheter with a 2-5-2 electrode spacing.

predefined ablation or procedural characteristics, as summarized in [Table 2]. In particular, there was no difference with respect to the total procedure duration, fluoroscopic time or time to bidirectional block. A steerable sheath was used in 2 patients in each group (p=0.275). Long-term outcomes are presented in [Table 2]. There was no recurrence of documented atrial flutter in any patient at one-year follow-up. Seventeen patients (34%) had symptoms of

palpitations after CTI-ablation (n=13 (35%) vs.n=4 (31%)p=0.775). Whereas, 19 patients (39%) had documentation of a different atrial arrhythmia (n=14(38%) vs .n=5 (38%)p=0.968). [Figure 2] shows a typical example of local electrograms from the MEs versus those derived from the conventional electrode at the onset of the critical RF application. Interpretable local electrograms were present on the MEs, but absent on the ablation catheter in 3 out of 13 patients. Local electrograms were detectable with both modalities in 8 out of 13 patients. Finally, there were no local electrograms detectable with

the MEs in 2 out of 13 patients. Hence, an additional diagnostic advantage was demonstrated in only 3 out of 13 (23%) of the patients. Notably, there was no difference in any of the ablation characteristics

Table 2: Procedural characteristics and follow-up

Procedural characteristics and follow-up	Abbott Safire N=37	Boston Scientific MIFI N=13	P value
Ablation:			
Number of RF-applications	6 [3.5-10]	8 [2.5-14]	0.838
Average duration per application (sec)	70.2 ±33.7	60.5 Å±22.6	0.343
Average temperature (Celsius)	49.5 Å±1.9	52.53 Å±3.5	0.059
Average impedance (ohm)	74.5 Å±5.6	74.2 Å±6.1	0.912
Average power (Watts)	46.4 Å±11.6	45.24 Å±12.9	0.365
Total ablation time (sec)	456 [263-661.8]	364 [181-821]	0.550
Procedure:			
Concomitant PVI	0	1(7.7)	0.260
Cross-over	0 (0)	0 (0)	-
Steerable sheath	2 (5.4)	2 (15.4)	0.275
Time to bi-directional block (min)	23 [12.5-37.5]	16 [3-23]	0.217
Fluoroscopic time (min)	13 [8-17]	18 [7-22]	0.631
Procedure time (min)	65 [53-80.5]	50 [34.75-73.25]	0.133
Follow-up:			
Recurrence of atrial flutter at one-year	0 (0)	0 (0)	
Recurrence of symptoms	13 (35.1)	4 (30.8)	0.774
Occurrence of other atrial arrhythmia	14 (37.8)	5 (38.5)	0.960

Pulmonary veins isolation (PVI). Mean Å±SD, numbers (%), median [25-75 percentiles].

in these patients with detectable electrograms on the MEs and the absence of the electrograms on the conventional electrode, also not with respect to the more frequent use of flecainide in the ME group. The recording in [Figure 3A] demonstrates a case where double potentials across the ablation line were recorded on the MEs but not on the conventional catheter tip. [Figure 3B] presents an example of a site of re-conduction after multiple ablation applications. Here also, small local electrograms were only observed in the MEs (box). In these cases, we were able to identify these electrograms recorded from the MEs but not from the conventional catheter tip.

Discussion

Major findings

This study is the first reporting follow-up data on atrial flutter ablation using an 8-mm ablation catheter with MEs. MEs detected local electrograms more accurately than the conventional large ablation electrodes in 3 out of 13 (23%) patients. Using MEs without a 3D mapping system resulted in similar procedure time, fluoroscopic exposure and RF time to achieve bidirectional block.

Previous studies

MEs in a conventional ablation catheter is a relatively novel catheter design and evidence supporting the efficacy of MEs in an 8-mm ablation catheter during CTI-ablation is lacking. In a small case series published by Tzeis et al., which included 6 patients, bi-directional block was achieved in allpatients, and procedural characteristics were comparable with the conventional 8-mm

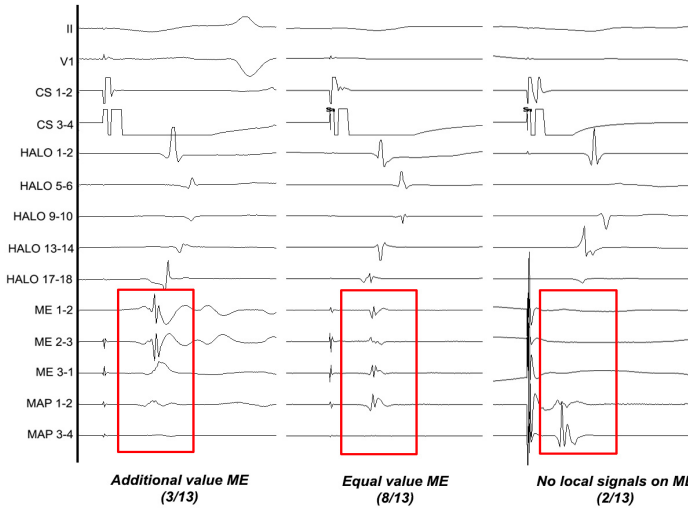


Figure 2: Intra cardiac electrogram before critical ablation point measured on mini electrodes (ME 1-2,2-3,3-4) and between the 8-mm electrode and the second electrode (MAP 1-2, boxes).

Table 1: Baseline characteristics

Baseline characteristics	Abbott Safire N=37	Boston Scientific MIFI N=13	P value
Male	31 (83.8)	11 (84.6)	0.944
Age	63.3 ±8	64 ±11.7	0.924
Body mass index	25.7 [22.2-30.3]	28.4 [24.2- 32.9]	0.201
Structural heart disease	20 (54.1)	10 (76.9)	0.148
Ejection fraction	53.7 ±12.4	51.4 ±10.2	0.639
Right atrium dilatation	11 (39.3)	6 (46.2)	0.678
Left atrium dilatation	17 (60.7)	7 (66.7)	0.722
Counterclockwise flutter	35 (100)	11 (84.6)	0.069
Clockwise flutter	5 (14.3)	2 (15.4)	0.622
Paroxysmal atrial flutter (<7days)	21 (65.6)	8 (61.5)	0.948
Persistent atrial flutter	11 (34.4)	4 (33.3)	0.948
Atrial fibrillation	21 (56.8)	5 (38.5)	0.256
CHA2DS2 VASc	2 (1-2)	3 (0.5-3)	0.482
Congestive heart failure	4 (10.8)	2 (15.4)	0.497
Hypertension	17 (45.9)	8 (61.5)	0.333
Diabetes	8 (21.6)	2 (15.4)	0.629
Stroke	2 (5.4)	1 (7.7)	0.604
Vascular disease	8 (21.6)	3 (23.1)	0.913
Beta blockers	27 (73)	8 (61.5)	0.439
Flecainide	3 (8.1)	5 (38.5)	0.010

Congestive heart failure, hypertension, age (75), diabetes, stroke, vascular disease, age (65), sex (CHA2DS2 VASc). Mean ±SD, numbers (%), median [25-75 percentiles].

ablation catheter^[13]. Iwasawa et al. performed a small prospective study in which they compared an 8-mm catheter with MEs with the conventional 8-mm and cryo ablation catheter. A high cross-over rate was observed in the MEs group (14 out of 25 patients, 56%), whereas no cross-overs occurred in the conventional group (0 out of 30). Also, there were 3 (out of 30) cross-over patients (10%) in whom a cryo ablation catheter was used. The high cross-over rate was explained by a decreased power delivery during temperature-controlled ablation due to an isolated temperature sensor^[12]. In our study, we observed a 100% procedural success rate in 13 patients treated with the ablation catheter with MEs. However, the additional diagnostic value of the MEs was seen in 23%, equal value in 62% and absence of ME electrograms in 15% of the patients in group B. We speculate that the lack of additional diagnostic value is partly due to the oblique positioning of the large electrode, resulting in floating MEs without tissue contact while the large ablation tip had sufficient tissue contact. Of note, one could argue that a point-by-point ablation strategy would be most appropriate when investigating MEs. However, our

a transmural lesion was formed after 25.9 ± 8.1 s in canine atria^[16]. Dragging the ablation catheter further after reduction of amplitude in the ME electrograms tended to create superficial transient lesions that needed additional ablation.

Multi-electrode diagnostic catheters with small electrode sizes and spacing are being employed for high and ultra-high resolution 3D maps of scar and dense scar, revealing areas of slow conduction^[17]. Voltage maps are more accurate when 1-mm electrodes with small inter-electrode spacing are used. Due to better sensing abilities, a 64% increase in amplitude was observed. This may result in a reduction in the total amount of dense scar in a 3D mapping system of one-third at a cut-off value of <0.05 mV and even two-thirds at a cut-off value of <0.25 mV. Remarkably, this difference was not found in healthy atria where the electrogram amplitude is generally high^[18]. Furthermore, smaller electrodes allow better annotation of fragmented electrograms during tachycardia and are associated with lower pacing thresholds during entrainment pacing^[18,19]. A lower pacing output reduces the amount of saturation of the amplifier, making electrograms during entrainment pacing better interpretable^[20]. Regarding the voltage cut-off values, decreasing these values will improve the visualization of channels within the scar. For these reasons it appears rational to use closely spaced electrodes, such as MEs, when searching for small channels of conduction. Also, the closer spacing and dimensions of the MEs allowed us to use stricter cut-off criteria for interpretable electrograms than in the conventional 8-mm tip recordings. Which value we should use to define scar is a subject of on-going discussion, and it remains unclear whether consensus voltage cut-off values are relevant to the CTI-ablation. Taken together, mapping techniques for visualization of small local electrograms are improving. Recording and localizing these specific electrograms using an 8- or 4-mm ablation catheter can be challenging, and MEs could be helpful in these cases. As displayed in two examples in Figures 3, electrograms may be present on MEs while not discernible on the conventional catheter tip, and can indeed be helpful in the assessment of the width of double potentials and the detection of reconnection. Indeed, also other manufacturers are now introducing similar technology to better identify small or fractionated local electrograms^[21].

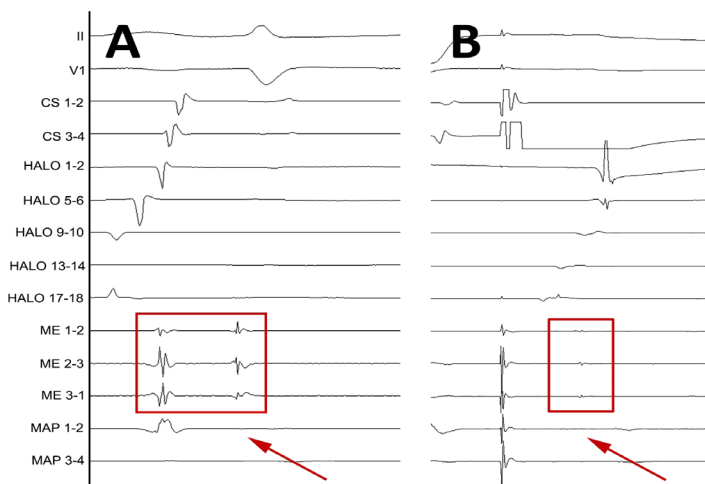


Figure 3: A, double potentials measured across the ablation line. Note, local signals were only observed on the ME (box). Whereas, no signals were observed on the conventional electrogram (MAP 1-2, arrow). B, intra cardiac electrogram of an area of re-conduction after multiple ablation applications. Small fractionated signals were only observed on the ME (box). Whereas, no signals were observed in the conventional electrogram (MAP 1-2, arrow).

study describes the use of MEs in a real-world clinical setting rather than in a randomized trial environment. The finding of a higher temperature in the MEs group in a previous study is in contrast with our findings^[12]. However, there was a trend towards higher ablation temperature in our MEs group (49.5 ± 1.9 vs. 52.5 ± 3.5 p=.059), but this did not influence the power delivery (46.4 ± 11.6 vs. 45.2 ± 12.9 p=.365) or the ability to create bidirectional block.

Clinical implications

In our experience, a small learning curve exists when using the MiFi Intellatip XP 8-mm ablation catheter. Reduction of ME electrogram amplitude can be misinterpreted as a marker of ablation lesion completion. Once ablation was started, ME electrograms rapidly disappeared. These findings are in concert with a previous study which described a rapid decrease of ME amplitude within 7.3 ± 3.9 s^[15]. Meanwhile, based on maximum ME amplitude attenuation,

Study limitations

This study is a single-centre retrospective study with a small sample size. The study is under powered for outcome analysis, mainly because an optimal success rate was achieved in both arms. Either point-by-point ablation or dragging with intermittent focal ablation was used depending on the preference of the operator and not systematically applied. Indeed, point-by-point ablation should have preference when searching for conduction gaps. However, our study describes the use of ME technology in a real-world clinical setting, and the proportion detectable and non-detectable MEs should be interpreted in that setting. Follow-up data was collected retrospectively, but all available rhythm recordings from referring hospitals were included in the analysis. However, despite these limitations, we were able to assess the absence of increased procedural or long-term efficacy of the CTI-ablation procedure.

Conclusion

In conclusion, the data show that MEs have added value to detect local electrograms in a fraction of patients. Our data did not show

a trend towards reduced effectiveness but suggest that MEs may allow omitting a 3D mapping system. Identifying local electrograms with MEs can potentially be helpful in specific cases where one is searching for small, local fractionated electrograms.

Disclosure

None.

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