PULSED FIELD ABLATION IN PATIENTS WITH CARDIAC IMPLANTABLE ELECTRONIC DEVICES - TECHNICAL ASPECTS OF INTERACTION: OBSERVATIONAL CASE STUDY

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Abstract

Pulsed field ablation (PFA) is a new method for treating cardiac arrhythmias. This method uses a sequence of high-voltage pulses to selectively destroy myocardial cells. The procedure can also be performed in patients with a cardiac implantable electronic device (CIED) such as a pacemaker (PCM) or an implantable cardioverter-defibrillator (ICD). The aim was to analyze such interaction of the pulse field and the pacing system. The interaction was assessed in two patients undergoing pulsed-field pulmonary vein isolation for paroxysmal atrial fibrillation in Liberec Regional Hospital. The first patient had a biventricular ICD, the CRT (cardiac resynchronization therapy) type. The second patient had a PCM, the 2D (dual-chamber) type. The signal waveform analysis was performed visually by an expert in real-time via the programmer (using real-time intracardiac electrogram) during each application of pulsed energy in the left atrium. The distance of the ablation catheter from the CIED sensing poles was <10 cm depending on the application in the left or the right pulmonary veins. On the intracardiac ECG, the interference from the PFA was detected by the device as an isolated cardiac event. In ICDs, the interference detection algorithm was also sporadically activated. There was no damage to the CIED electronics during PFA. CIED electronics is protected against high-energy pulsed fields used in these kind of interventions. Impulse interference is not a significant risk for affecting the stimulatory function of the CIED. All CIEDs have limits in signal processing as they are targeting the heart signal frequency range. The signal envelope from these high-frequency applications can be seen on the intracardiac ECGs. The signal processing parameters of CIEDs and the effect on pacing function may vary across different systems.

Keywords

electrophysiology pulsed field ablation (PFA), cardiac implantable electronic device (CIED), signal analysis, electromagnetic interference (EMI)

Introduction

Pulsed field ablation (PFA) is mainly used to isolate pulmonary veins in patients with atrial fibrillation. PFA is a nonthermal method using high-voltage pulses to target tissue. This application destabilizes cell membranes by forming irreversible nanoscale pores, culminating in cell death. Various tissues have different threshold field strengths that cause necrosis. Cardiomyocytes have among the lowest threshold values of any tissue [1].

Cardiac implantable electronic devices (CIEDs) operate by sensing electrical potentials from the distal end of intracardiacally inserted leads. Oversensing of interference signals can result in affecting the device function in the form of inhibition of pacing or inadequate therapy in ICDs. There is also a risk of damage to the CIED electronics when exposed to strong electromagnetic fields (EMFs) such as PFA [2]. However, according to the available studies on this topic [3], no clinically significant interaction has been observed due to PFA in different CIEDs. In this paper,

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we described the protective mechanisms of CIEDs and analyzed the device response to this type of EMFs. We analyzed the real-time interaction on two different CIEDs in patients undergoing the bipolar PFA procedure.

Materials and Methods

Principle of PFA

PFA uses high-voltage pulsed electrical energy to selectively destroy cardiomyocytes. The energy is delivered bipolarly between the individual splines and their electrodes. It is mainly used for pulmonary vein isolation. Special ablation catheter (12-F Farawave) contains 5 splines, each containing 4 poles. Farawave applies five sequences of 2 kV biphasic bursts in the ostium of the left and right pulmonary veins. One application takes about 2.5 s, with each burst lasting up to 200 ms. The burst consists of hundreds of different µs pulses. The signals from the electrophysiological recording device are shown in Fig. 1.

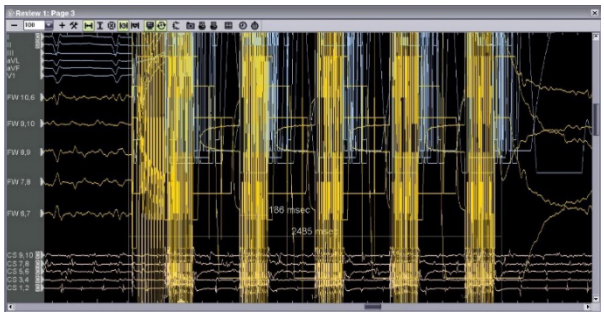

Fig. 1: Intracardiac recording during PFA pulmonary vein isolation from Prucka recording system. Signal from surface ECG, Farawave catheter, decapolar catheter in coronary sinus. Duration of burst <200 ms and duration of one application <3 s. Sweep speed 100 mm/s.

The Farawave catheter (Boston Scientific, USA) is <10 cm from the sensing poles of the atrial and ventricular leads of CIED during applications. The distance varies according to the application site. In our CIED patients, Farawave distances from the electrode tip ranged 2–10 cm. The position of the catheter in relation to the CIED leads is shown in various x-ray projections in Fig. 2, Fig. 3 and Fig. 4. The PFA catheter can be configured into two different shapes (to a semi-deployed basket pose or to a fully deployed flower configuration) [3].

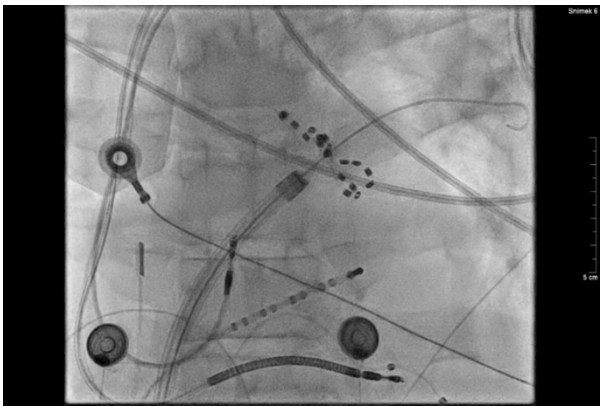

Fig. 2: Anteroposterior x-ray projection of Farawave catheter in left pulmonary veins in patient with implanted ICD.

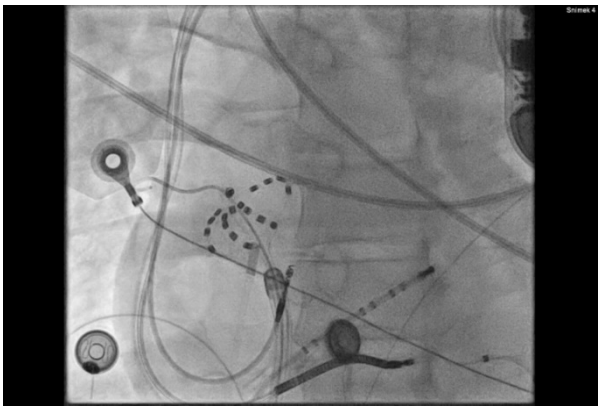

Fig. 3: Left anterior oblique x-ray projection of 15° of Farawave catheter (basket configuration) in right pulmonary veins in patient with implanted ICD.

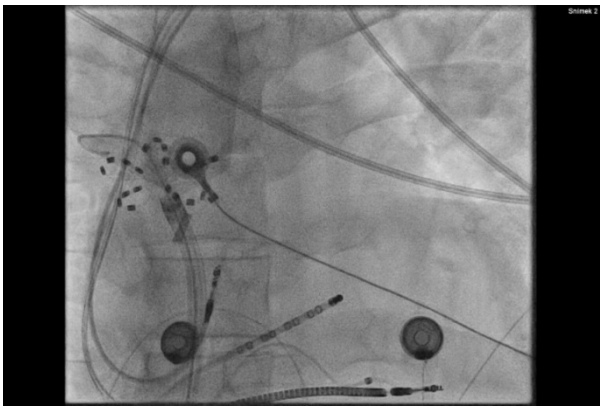

Fig. 4: Right anterior oblique x-ray projection of 15° of Farawave catheter (flower configuration) in right pulmonary veins in patient with implanted ICD.

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Protection of CIEDs against high voltage pulses

When high-voltage electrical pulses are applied, the cells lose their capacitive properties, and the tissue becomes a good conductor [4]. The CIED electronics is protected against strong electric fields. The electronic circuits are shielded in a closed metal case that works as a Faraday cage. The circuits are protected against high-energy EMFs by a Zener diode near the connection of the leads to the generator. This works as a short-circuit circuit that passes current in the opposite direction away from the CIED when the detected voltage exceeds the voltage value above the output value of the pulse generator [5].

Signal processing in CIEDs and its limitations

The raw electrogram (EGM) passes from the sensing poles to the connectors through a hermetic grommet with high-pass filters and high-voltage protection. Then, it reaches the sensing circuits. Current CIEDs use digital circuits for signal processing. Sampling is the process of converting an analog signal into a digital sequence of sampled voltages. According to Nyquist's theorem, a periodic signal must be sampled at more than twice the highest frequency component of the signal. The quality of this step depends on the sampling frequency, voltage range and sampling accuracy (voltage gain of the least significant bit), frequency range, dynamic range of the amplifier, and quantization noise. The filtered signal is further amplified. Then, the digital signal is band-pass filtered to remove deviations from the baseline and to select a given frequency range. The next step is the rectification step, after which all signals are represented by their absolute magnitude. This removes the polarity information. The sensing step occurs when the rectified EGM reaches a threshold voltage value [5, 6].

Processing parameters for intracardiac signals are not available from CIED manufacturers and may vary. The CIED primarily senses useful signals in the 10–100 Hz range where intracardiac signals are present. Frequencies outside this range are filtered in various ways. The sampling rate of the CIED is 256, 512 or 1024 Hz for the most advanced devices. The sampling rate also varies for the raw signal that the CIED is working with, for the real-time displayed EGM, and for the EGM stored in the device memory (varies depending on the number of sensing channels). This implies that higher frequency signals cannot be adequately sensed by the CIED. Aliasing, distortion of the figured signal and loss of information occurs. Therefore, we can see something like a signal envelope of such an EGM.

For the CIED detection, the maximum signal amplitude in a short time interval after exceeding the CIED sensitivity is crucial. The EMG must be sensed in the alert window to affect the pacing function of the CIED. Therefore, the timing of the signal is important. Different intervals of absolute and relative refractory periods are used, where the signal is completely blanked out or is only reflected in the counters but does not affect the pacing function of the device. The aim of these timing intervals is to cover unwanted signals.

Modern CIEDs have also software features to reduce electromagnetic interference (EMI) oversensing. Algorithms such as Noise Reversion (NR) in Biotronik (BIOTRONIK SE & Co. KG, Berlin, Germany) CIED or Noise Reversion Mode (NRM) in Abbott CIED are designed to protect the patient in the presence of EMI from pacing inhibition or inadequate therapy in the case of ICDs. The device response can be programmable. This change is usually triggered by signals detected during the noise sampling period (NSP) within the stimulator timing cycle, after a sensed or paced event. The NSP lasts from 50 to 200 ms. If an event is detected during this interval, it is interpreted as noise and the refractory interval is restarted. In 2D CIEDs, the PVARP (postventricular atrial refractory period) interval is also restarted at its upper limit. If additional noise is detected in the NSP, the refractory interval or NSP is further restarted and the PCM does not recognize cardiac signals at this time. Repeating noise events eventually cause the interval for the lower limit of the pacing frequency to expire, and a pacing pulse is delivered. Continuous noise leads to asynchronous pacing at the lower frequency limit. This is how non-programmable NR works in the PCM manufactured by Biotronik [5, 7].

In ICDs, the noise detection is different due to the possible detection of ventricular fibrillation. They have shorter NSP periods. The new programmable NRM algorithm in the Abbott CIED differs from previous algorithms. The NRM detects multiple fast signals in a fixed time window (up to 16.7 Hz) and additionally includes two noise windows that are compared to each other in the case of initial detection. The sensing windows (sampling window and confirmation window) last 125 ms after the primary sensing event. Signals must be sensed in both of these windows to be evaluated as noise. Once the noise is confirmed in the next window, the device switches to the NRM preset and to asynchronous pacing according to the base rate or according to the sensor rate. High frequency noise with six or more baseline transitions within the noise sampling period (62.5 ms) will be immediately classified as noise and activates the NRM response [8].

Clinical cases

Both patients with implanted CIEDs were appropriately indicated for PFA. Signal analysis was performed visually by an expert by monitoring the intracardiac electrocardiogram via a programmer. The intracardiac signals were monitored by the intracardiac electrodes of the pacing device. The application of

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a pulsed field or other electromagnetic interference is shown by the presence of non-physiological potentials on the pacemaker sensing channels. The analysis was performed in real-time.

The first patient was 41 years old man with implanted Abbott ICD CRT Quadra Assura MP (Abbott, Illinois, USA) since 2020. Parameters of the CIED programming are in Table 1. The Low Frequency Attenuation filter was set On. The patient had sinus rhythm with intrinsic ventricular conduction (Vs) during ablation. The programmable NRM was set to inhibit pacing and tachytherapy. The basic timing parameters were rate adaptive. The real-time EGM from the ICD when pulse energy is applied is shown in Fig. 5.

Table 1: Basic programming and refractories of Abbott ICD in patient undergoing PFA.

Parameter	Value
Mode	DDDR
Base Rate/Max Track Rate	60/130 bpm
Auto Mode Switch (Detection Rate)	DDIR 60 bpm (180 bpm)
V. Noise Reversion Mode	Pacing Off
A/V Sense Configuration	Bipolar/RV Bipolar
Sensitivity	Auto/Auto
Max Sensitivity	0.3/0.5 (Pacemaker, Defib) Mv
A/V Sense Refractory	93/125 ms
Post-Vent. Atrial Blanking/Vent. Blanking	70/52 ms
PVARP/Shortest PVARP (V ref)	275/225 ms

A—atrial, V—ventricular, PVARP—post ventricular refractory period.

The second patient was 72 years old man with the Biotronik 2D PCM (Enitra 8 DR-T) implanted in 2019. Parameters of the CIED programming are in Table 2. The patient had atrial fibrillation with right ventricular pacing (Vp).

Table 2: Basic programming and refractories of Biotronik PCM in patient undergoing PFA.

Parameter	Value
Mode	DDDR
Base Rate/Max Track Rate	60/130 (WKB) bpm
Mode Switching (Detection Rate)	DDIR +10 (160 bpm)
A/V Sensing Polarity	BIPL/BIPL
A/V Sensitivity	0.6/5.5 mV
PVARP/Auto PVARP	325 ms/On
Atrial Refractory Period	AUTO
Ventricular Refractory Period	250 ms
Far-field protection after Vs/Vp	100/150 ms

A—atrial, V—ventricular, PVARP—post ventricular refractory period, WKB—Wenckebach limit.

Results

No signs of damage to the CIED electronics were found in both patients. The values of the CIED electrical parameters (impedances, sensing, thresholds) remained stable. There was no interruption of telemetry due to PFA. In both patients, there was no clinically significant effect on the pacing function during PFA.

In the first ICD patient (Fig. 5), the interference during pulsed energy application was sensed on both atrial and ventricular bipolar detection channels. The EMI signal was first sensed as an isolated intrinsic event, which inhibited pacing and reset the pacing counter. This was followed by EMI at each NSP within the ventricular refractory period after the sensed event (Vs). This activated the NRM, which inhibited pacing and tachytherapy for the duration of a single PFA application (<3 s). No detection of ventricular fibrillation (VF) occurred.

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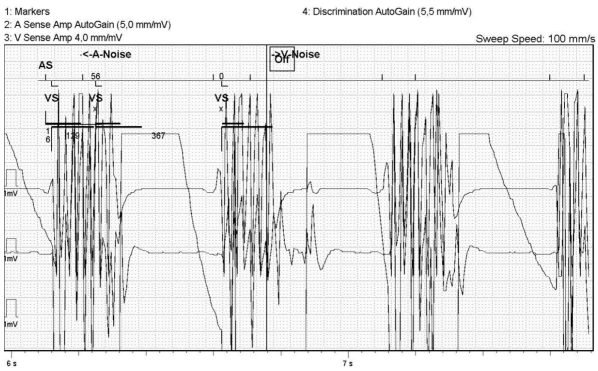

Fig. 5: Real-time intracardiac EGM in patient with Abbott ICD during pulsed field ablation procedure. EMI of PFA is interpreted as isolated ventricular sense (Vs) and as ventricular noise (V-noise).

The second patient with PCM (Fig. 6) had a low sensitivity setting on the ventricular channel (5.5 mV). Therefore, EMI was sensed only on the atrial bipolar channel. The EMI signals at each burst fell into different atrial refractory intervals (e.g., also far-field protection interval or PVARP). With continuous interference, this would lead to a reset of the refractory interval and to asynchronous pacing. With such a short EMI occurrence, the asynchronous pacing did not occur. The patient had the atrial fibrillation and active MS (Mode Switching). The pacing was controlled by the ventricular timing. The presence of EMI on the atrial channel had no effect on the pacing function of the PCM.

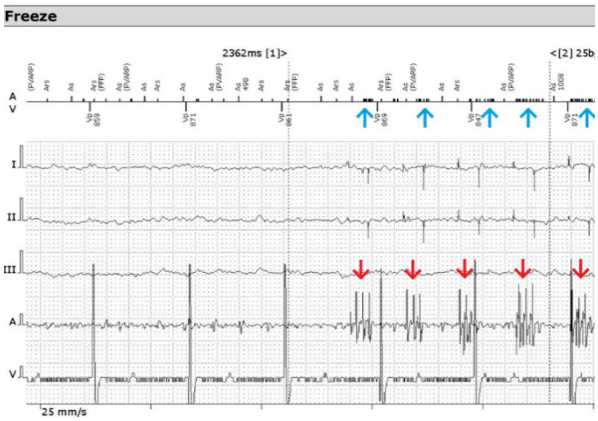

Fig. 6: Real-time intracardiac EGM in patient with Biotronik PCM during pulsed field ablation procedure. EMI of PFA is marked as atrial noise in atrial refractory period. Blue arrows highlight the detection of atrial interference in the markers channel. Red arrows indicate non-physiological signals in the atrial channel.

Discussion

The processing and displaying the EMI signals on the EGM of CIEDs is limited by the technical options of the CIED. The CIED uses digital circuits and primarily targets signals from the heart signal spectrum (10–100 Hz). Thus, we can see only partial information (rather a signal envelope) of such signals on the EGM. Effect of EMI on the CIED function is affected by the device mode, sensitivity and configuration. Also, the setting of timing functions is crucial. Timing parameters in current CIEDs are mostly dynamic or rate adaptive.

The PFA does not seem to be dangerous for CIEDs. There is no risk of prolonged pacing inhibition (>3 s) or oversensing EMI as ventricular fibrillation. The question is if a CIED intervention is necessary for the PFA procedure. Of course, for a more detailed signal analysis on a larger sample of patients, it would be useful to use appropriate software tools and standardized metrics. For radiofrequency ablations, modification of PCM programming or deactivation of therapies for ICDs was necessary. However, as the PFA is a new method, there is still not a lot of published data available.

Conclusion

Both patients underwent the PFA method using the pulsed field system. Impulse interference did not seem to be a problem for the effect on the pacing function of such CIEDs used in our analysis (Abbott ICD, Biotronik PCM). The pulsed field system uses bipolar energy application. Despite the minimal distances of the Farawave catheter from the CIED lead poles, EMI may not be sensed at all at lower sensitivities. Damage to the CIED due to strong field may be more severe, but CIEDs are protected against such EMFs. The CIED function and parameters in both patients were good after the procedure and also during further long-term follow-ups.

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Ethical Statement

The research was conducted in accordance with the principles embodied in the Declaration of Helsinki and in accordance with local statutory requirements and ethical standards. Ethics committee approval was not required for this type of observational study.

Conflict of Interest

The authors declare no conflict of interest.

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