Validation of leadless atrioventricular synchronous pacing with Holter-ECG: a pilot study

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Background: The novel MICRA AV leadless pacemaker can provide atrioventricular (AV) synchronous pacing using an accelerometer-based atrial sensing algorithm.
Purpose: To describe the performance of MICRA AV pacemaker in a real-life setting and to determine the agreement between AV synchrony determined by the device counters and AV synchrony obtained by a 24 h ECG Holter test.
Methods: This pilot study included the first ten patients implanted with a MICRA AV leadless pacemaker at our institution. All implants were performed according to standard protocols and under deep sedation. A close follow-up was performed, and atrial sensing parameters were adjusted following AV synchrony given by the device counters. Patients underwent a 24 h ECG Holter test once AV synchrony remained stable for at least two months. The ECG Holter signal was analyzed in a blinded manner by an automatic delineation system based on the wavelet transform (Figure). This algorithm has a sensivity of 98.9% and a positive predictive value of 91.9% to detect p waves. Cardiac cycles were defined as synchronous if a QRS complex followed the P-wave by ≤300 ms, according to MARVEL 2 study criterion. AV synchrony obtained from the 24 h Holter test was compared with AV synchrony extracted from the device counters (AM-VP + AM-VS) during the same 24 h.
Results: From June to November 2020, 10 patients (7 males, mean age 83.5±5.4) were implanted with a MICRA AV leadless pacemaker (5 patients due to complete AV block and 5 patients due to second degree AV block). All devices were implanted after 1 deployment and no major complications appeared. Data related to implant parameters are displayed in Table 1. Device reprogramming was needed in all patients during follow-up. The 24 h ECG Holter monitoring was performed 141.4±45 days after the implant (mean time). Device settings and programming at Holter date is displayed in Table 1. Total ECG recorded time was 210.6 h and 915,488 cardiac cycles were analyzed. The mean percentage of synchronous cardiac cycles was 88.6±8.5% of total cycles while the mean AV synchrony determined by the device counters (AM-VP + AM-VS) during those 24 h was 89.8±5.5%. A good patient to patient correlation between these two measures was found (coefficient of intraclass correlation = 0.72).
Conclusions: We obtained high rates of AV synchrony with MICRA AV leadless pacemaker, in our short-term follow-up pilot study. Manual adjustment of the atrial sensing parameters, guided by the device counters, seems to be useful to obtain an optimal performance.

Table 1. Implant data and functioning/programming data at Holter date.

Implant	
• Fluoro time (mean ± SD)	9.2±14.6 min
• Location (n)	
○ High-septum	5
○ Mid-septum	3
○ RVOT	2
• R wave (mean ± SD)	13±4.4 mV
• Impedance (mean ± SD)	1004±273.7 Ohms
• Threshold (x 0.24 ms) (mean ± SD)	0.66±0.43 Volts
Holter date	
• R wave (mean ± SD)	16.1±5.5 mV
• Impedance (mean ± SD)	690±214.9 Ohms
• Threshold (x 0.24 ms) (mean ± SD)	0.55±0.51 Volts
• AV conduction (n)	
○ Intact	1
○ Paroxismal AV block	3
○ 2º degree AV block	5
○ Complete AV block	1
• Programming (n)	
○ VDD 40/105	7
○ VDD 50/105	3
• Vector (n)	
○ 1+2	3
○ 1+3	1
○ 2+3	5
○ 1+2+3	1
• A3 threshold (mean ± SD) *	8.0±3.1 m/s²
• VE window (mean ± SD) **	620±25.8 ms
• A3 threshold (mean ± SD) *	2.9±1.3 m/s²
• A4 amplitude (mean ± SD)	4.4±1.4 m/s²

*Automatic
**Fix

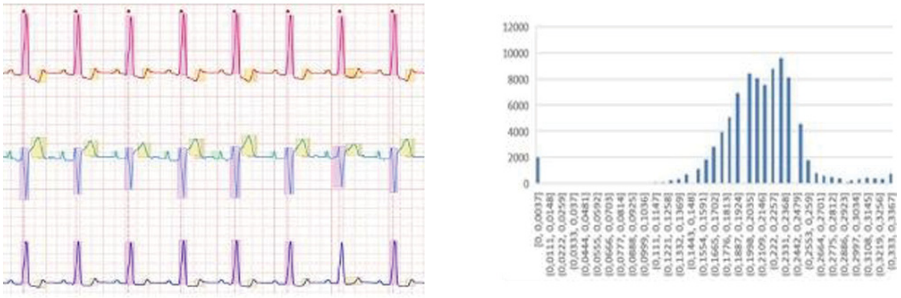

Figure. Example of the automatic ECG waves delineation performed by the wavelet transform algorithm (left). P-QRS intervals histogram (right) obtained after ECG analysis.