Rate-dependent change in capture threshold following implantation of a leadless pacemaker

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Introduction

Implantation of a conventional transvenous cardiac pacemaker has historically been the standard of care for patients with symptomatic bradycardia or high-degree atrioventricular (AV) block.[1] Capture threshold, lead impedance, and sensing voltage amplitude are essential parameters to assess and predict conventional pacemaker lead performance during the initial implantation procedure and for long-term follow-up.[2,3] Recently developed leadless pacemakers such as the Micra AV and VR systems (Medtronic Inc, Minneapolis, MN) have unique advantages over conventional transvenous cardiac devices and have been implanted in suitable patients for the past 5–6 years.[4] During Micra implantation, capture threshold, sensing voltage amplitude, and lead impedance are also measured to assess if the location and fixation of the device are suitable for final deployment. Capture threshold of a pacing lead is a measurement of the minimal voltage required to activate the myocardium, and initial Micra clinical trials have used a capture threshold of $\leq$1.0 V at 0.24 ms as the most important parameter during initial implantation.[5] In general, if initial capture threshold is above 1.0 V at 0.24 ms, guidelines recommend to retract the device and redeploy to a different location until the recommended capture threshold is achieved. Capture threshold is also a key measurement to predict the long-term performance of the Micra.[6] Therefore, the capture threshold is a critical measurement for both the initial implantation and the prediction of long-term outcome of the device.

While testing lead performance during pacemaker implantation, the myocardium is paced at a rate slightly above the intrinsic heart rate to assure myocardial capture via pacing. There is no consensus on how increased the pacing rate should be from the intrinsic rate during measurement. Here the authors report a clinical case of Micra implantation that demonstrated varying capture thresholds at different pacing rates. This case challenges the conventional method of testing capture threshold during Micra implantation and may motivate additional study to improve the assessment of lead performance at implant to ensure both short- and long-term success of the procedure.

KEY TEACHING POINTS

- Capture threshold is the most important parameter to assess leadless pacemaker performance at initial implantation and to predict long-term outcomes of the device.
- In rare cases, the capture threshold of leadless pacemakers, in addition to that of their traditional counterparts, can change substantially at different pacing rates.
- Pacing at different rates during capture threshold testing of a leadless pacemaker may be indicated to ensure adequate assessment of pacemaker success.

Case report

A 98-year-old man with a past medical history of paroxysmal atrial fibrillation and chronic obstructive pulmonary disease presented to the authors' institution for multiple episodes of presyncope. During the night following admission, the patient developed new second-degree type 2 AV block with syncope. He later experienced multiple witnessed syncopal events and bradycardia with heart rate decreasing to the 30s (beats per minute; bpm) and pauses up to 5 seconds. The patient was started on transcutaneous pacing and dopamine infusion, and was taken to the catheterization laboratory for placement of a temporary transvenous pacing wire via right internal jugular access. This temporary wire subsequently developed issues with intermittent noncapture that did not resolve with serial adjustments, and it was removed.

KEYWORDS Capture threshold; Pacing; Leadless pacemaker; Bradycardia; Electrophysiology devices; Pacemaker implantation
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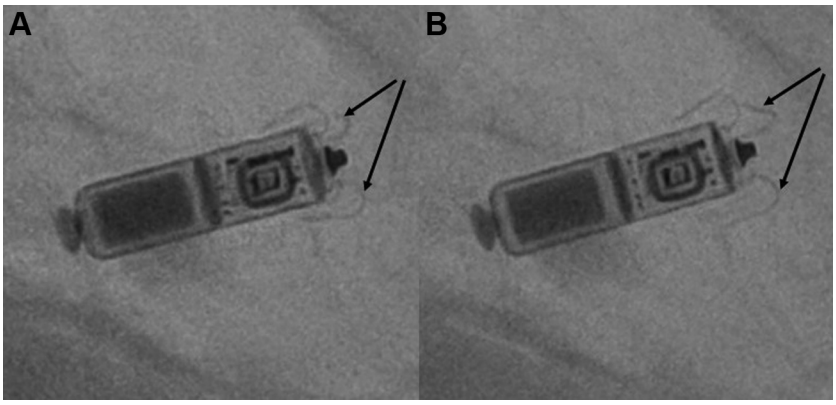

Figure 1 The Micra leadless pacemaker (Medtronic Inc, Minneapolis, MN): before (**A**) and after (**B**) pull-and-hold test. Note the 4 tines (*black arrows*) on the distal end of the Micra device that adhere to the myocardium. Opening of the tines after the pull-and-hold test, as seen in Figure 2B, is an indicator of adequate fixation.

After consultation with the patient and his family, a Micra AV leadless pacemaker was implanted. The Micra AV is a recently approved model with AV synchrony, indicated in patients with AV block. At the implant device deployment step, the patient had intrinsic sinus rhythm and intact AV conduction with heart rate in the 70s (bpm). Following the manufacture-recommended protocol, the Micra pacemaker was deployed at the right ventricular middle septum with "gooseneck" shape of delivery sheath suggesting adequate contact of myocardium. Two of the 4 tines were observed to engage the septum on pull-and-hold test under fluoroscopy (Figure 1). The pacing capture threshold was tested manually in VVI (ventricular demand pacing) mode at a pacing rate of 100 bpm, and the pacing threshold was 0.5 V @ 0.24 ms at this rate (Table 1). R waves were approximately 5.3 mV and impedance was 710 ohms. As all numbers were within the manufacturer-recommended values (R-wave amplitude $\geq$5 mV, impedance 400–1500 ohms, and threshold $\leq$1.0 V at 0.24 ms) and to avoid unnecessary procedure risks in the frail patient, the device was deployed at this location.[7] Immediately after removing the tether, the device was tested again with the same capture threshold, sensing amplitude, and impedance. The rest of the procedure was completed smoothly with delivery sheath removal and closure of the groin access site. Final programming was set to VDD (single-lead atrial synchronous pacing) mode with a lower rate limit of 60 bpm. However, intermittent loss of capture was observed at the pacing rate of 60 bpm. Threshold testing was performed again at a rate of 100 bpm and the threshold remained 0.5 V @ 0.24 ms. A subsequent test at a rate of 60 bpm then showed a threshold of 2.5 V @ 0.24 ms. The Micra sensing voltage and impedance were unchanged from the intraprocedure measurements.

The device was set to an output of 4.0 V @ 0.24 ms, and an immediate postprocedure chest radiograph showed stable device location in the right ventricle, similar to the intraprocedure location (Figure 2A). Approximately 3 hours after implant, the device was reinterrogated. The threshold remained 0.5 V @ 0.24 ms at a pacing rate of 100 bpm. Because the intrinsic rate was above 70 bpm, the device was temporarily set at a rate of 80 bpm with an output of 1.5 V @ 0.24 ms. No loss of capture was observed. The output remained set at 4.0 V @ 0.24 ms following this interrogation. On the morning following implantation, a chest radiograph confirmed unchanged device location in the right ventricle (Figure 2B). The capture threshold was 1.75 V @ 0.4 ms at a rate of 90 bpm. A threshold test was performed at a rate of 60 bpm with a resulting threshold of 2.5 V @ 0.4 ms. The sensing voltage and impedance remained largely unchanged from the intraprocedure numbers. The final lower rate was set at 60 bpm. To ensure an adequate safety margin, the pacing output was left at 4.5 V @ 0.4 ms and auto threshold capture management was turned off, which correlated to a predicted battery life of 2.5 years. Owing to the patient's comorbidities and predicted life expectancy, the electrophysiology team decided to closely monitor him clinically without performing Micra extraction or reimplantation. He remained in sinus rhythm during the remainder of his

Table 1 Heart rate vs capture threshold of Micra pacemaker, during the periprocedural period and 2 weeks following procedure

Heart rate (beats/min)	Capture threshold (V)				
	Intraprocedural	Immediately postprocedure	Three hours postprocedure	One day postprocedure	Two weeks postprocedure
100	0.5 (@ 0.24 ms)	0.5 (@ 0.24 ms)	0.5 (@ 0.24 ms)		1.25 (@ 0.24 ms)
90				1.75 (@ 0.4 ms	
80			1.5 (@ 0.24 ms)		
60		2.5 (@ 0.24 ms)	2.5 (@ 0.4 ms)	2.5 (@ 0.4 ms)	1.13 (@ 0.4 ms), 0.88 (@ 0.4 ms)

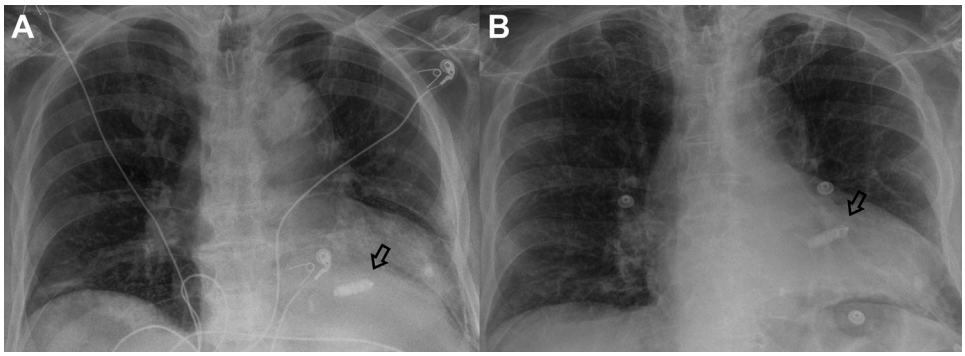

Figure 2 Chest radiographs demonstrating location of the Micra pacemaker (Medtronic Inc, Minneapolis, MN), both immediately (**A**) and 1 day (**B**) following implantation. The position of the Micra pacemaker remained unchanged on chest radiograph (*arrow*).

admission and was discharged to a rehabilitation facility with planned follow-up in electrophysiology clinic.

Two weeks later, the patient was readmitted to the hospital owing to COVID-19 pneumonia. His Micra leadless pacemaker was interrogated again, and he was found to be ventricularly paced 98% of the time. The capture threshold was 1.25 V @ 0.24 ms when pacing at 100 bpm, and when paced at 60 bpm the capture threshold was 1.13 V @ 0.24 ms and 0.88 V @ 0.4 ms. Both sensing voltage amplitude and lead impedance were unchanged from the previous interrogation. To ensure adequate safety margin, the Micra output was reprogrammed to 2.5 V @ 0.4 ms, which correlates to an estimated battery life of 4 years.

Discussion

Though rare, bradycardia-associated rise in capture threshold has been noted in the immediate postprocedural period following pacemaker implantation.[8] The mechanism for this increase is yet uncertain. Proposed etiologies include micro-dislodgement of leads and inflammation-induced phase 4 block.[9,10] Such rise in capture threshold may lead to unnecessary intervention, as the increase appears to spontaneously resolve in most instances. Of the handful of existent literature cases regarding rate-dependent elevation in capture threshold, all have involved traditional single-chamber, dual-chamber, or biventricular pacemakers. To the knowledge of the authors, no case of bradycardia-associated increase in pacemaker capture threshold has yet been published following implantation of a leadless pacemaker, a relatively recent and increasingly common option that has previously demonstrated reduced rates of complications when compared with traditional transvenous pacing. Here, the authors describe a unique case of rate-dependent increase in capture threshold after leadless pacemaker implantation. At faster pacing rates the capture threshold was much lower and adequate, while at slower pacing rates the capture threshold increased considerably.

The Micra transcatheter pacemaker is a single-chamber ventricular pacemaker directly implanted inside the right ventricle. Four flexible nitinol tines on the cathode of the device help to fix the device position.[7] Typically, at least 2 of the 4 tines should demonstrate adequate fixation during device implantation. Device parameters including capture threshold, sensing voltage amplitude, and impedance are measured during the procedure. The body of the device is free within the ventricle and uses the tines to secure its location on the endocardium. The authors speculate that in this case, the initial deployment of the Micra had suboptimal fixation of the device to the myocardium. At higher heart rates the diastolic period is shorter and distance of myocardial movement is reduced, while at lower heart rates the diastolic phase is longer and there is greater movement of the myocardium. Therefore, when the device was initially checked at the higher pacing rate of 100 bpm, the contact of the device to the myocardium was adequate and demonstrated good capture threshold at the implantation. However, postprocedure, when the device was reprogrammed to a slower rate of 60 bpm to minimize pacing and conserve battery life, the contact of the device to the myocardium was suboptimal owing to the larger excursion of the myocardium during diastole, increasing the capture threshold. The device pacing output was adjusted to a higher setting to ensure an adequate safety margin, which in turn shortened battery life.

Unlike conventional transvenous pacemaker leads, the Micra leadless pacemaker uses only tines to fix the body of the device to the myocardium. When implanting a Micra, one relies on tine fixation movement prior to deployment and measurement of lead parameters to confirm adequate device contact to the myocardium. After the tether is removed and the device is deployed, recapture and redeployment of the device are more difficult in comparison to traditional transvenous pacemakers. In this case, all lead parameters were adequate and 2 of 4 tines were confirmed to be attached prior to the device deployment, in accordance with the standard implant protocol recommended by the manufacturer. The authors speculate that increased capture threshold at lower pacing rates was due to suboptimal device contact with the myocardium during the longer duration of diastole.

This case highlighted rate-dependent capture threshold changes for a Micra leadless pacemaker. Capture threshold

is one of the most important parameters to assess the adequacy of device contact to the myocardium and to predict both the outcome of device performance and the longevity of the battery.[6] Therefore, adequate capture threshold is of paramount importance for device success. This case highlights the value of measuring capture threshold at different pacing rates to confirm adequate thresholds. To the knowledge of the authors, there is no recommendation to assess capture threshold at different pacing rates during Micra implantation. In situations such as this case, these measurements may be indicated to confirm adequate fixation of the device to the myocardium, an important indicator of device safety and longevity. Thus, the authors recommend including the measurement of capture threshold at different pacing rates as part of the standard Micra implantation protocol.

Conclusion

Bradycardia-associated increase in capture threshold may occur after implantation of leadless pacemakers. As in previously documented cases of rate-dependent capture threshold rise following implantation of traditional pacemaker models, this occurrence in leadless pacemakers may be recognized by pacing at both a higher and lower rate and observing changes in capture threshold.

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