

# Nanostim leadless pacemaker system: A longer waiting period after active fixation may reduce unnecessary repositioning

Hiro Kawata, MD, PhD,<sup>\*</sup> Pranav M. Patel, MD,<sup>\*</sup> Rajesh Banker, MD, MPH<sup>\*†</sup>

From the <sup>\*</sup>University of California Irvine Medical Center, Orange, California, and <sup>†</sup>Hoag Hospital, Newport Beach, California.

## Introduction

Cardiac pacing has been an established therapy for patients with bradyarrhythmias. In conventional pacemakers, lead-related complications such as venous obstruction, insulation fracture, and lead-related infection are the main concern after pacemaker implantation. Recently leadless pacemaker systems (LPS) were developed and now function to overcome these lead-related complications.

The Nanostim LPS (St Jude Medical, St. Paul, MN) can provide pacing for bradyarrhythmias. This system is a pulse generator with built-in battery and electrodes for implantation in the right ventricle. It is well known that in conventional pacing systems the pacing thresholds of implanted leads tend to rise initially owing to tissue injury surrounding the implanted pacing lead.<sup>1</sup> These initially high pacing thresholds tend to attenuate within the first 5–10 minutes after implantation. However, if these high pacing thresholds remain after this period of time, then repositioning of the conventional pacemaker lead may be considered. The behavior of pacing thresholds in LPS is not well documented. We report on 2 patients with LPS in whom pacing thresholds showed differing behavior from conventional pacemaker systems.

## Case reports

### Case 1

A 71-year-old man with a history of symptomatic 4 seconds of asystole (documented on an insertable cardiac monitor) was admitted for the Nanostim LPS implant. An initial right ventriculogram was used to identify an appropriate implant location (Figure 1). An apical septal location was selected. The LPS was actively fixed in place and then positioned into tethered mode. The R-wave amplitude was documented as >12.0 mV and the

impedance of the device was 1830 ohm. Initial pacing thresholds were higher than 6.5 V. As the location was favorable, the decision was made to wait rather than reposition the LPS. After 30 minutes, the threshold went down to 2.25 V at a pulse width (PW) of 0.4 ms. As the threshold had down-trended to an acceptable value, we released the LPS into the right ventricle (Figure 2). The following day, interrogation revealed that the threshold had decreased to 0.5 V at a PW of 0.4 ms, and the impedance decreased to 1520 ohm.

### Case 2

A 72-year-old man with a low functional capacity developed a high-degree atrioventricular block and was admitted for an LPS implant. The LPS was implanted in the same manner as described in case 1. Initial R-wave amplitude was 3.0 mV, with an impedance of 1330 ohm; and pacing threshold could not be measured (>6.5 V). Considering the ideal apical septal anatomical location, the decision was made to wait and monitor rather than reposition the LPS. Twenty-five minutes post implant, the threshold attenuated to 2.0 V at a PW of 0.4 ms. The LPS was released into the right ventricle. Interrogation of the implant the following day revealed that the threshold was 0.5 V at a PW of 0.4 ms, and the impedance decreased to 800 ohm.

## Discussion

After implantation of pacing leads, the pacing threshold may vary over time. In conventional pacing systems, pacing thresholds of active-fixation implanted leads tend to rise initially owing to tissue injury.<sup>1,2</sup> These leads can cause tissue injury, and therefore adequate pacing thresholds may not be obtained immediately. It is likely that the trauma caused by extension of a screw helix into the myocardium is responsible for this hyperacute evolution of the intracardiac electrogram. In conventional pacemaker systems with conventional active-fixation leads, a high pacing threshold of >2.25 V (after a waiting period of 5–10 minutes) should be considered for possible repositioning.<sup>3</sup>

The behavior of pacing thresholds of leadless pacemakers after initial implantation has not been well known. Recently

---

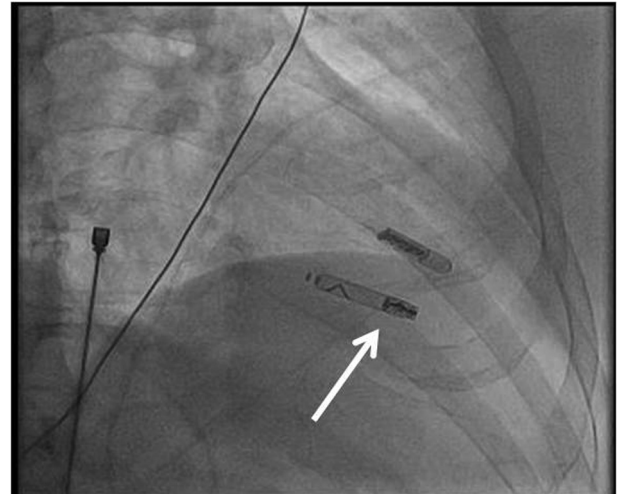
**KEYWORDS** Leadless cardiac pacemaker; Nanostim leadless pacemaker; Pacing threshold; Pacemaker; Right ventricular lead (Heart Rhythm Case Reports 2018;4:63–65)

---

Dr Banker receives research grants and consulting agreements from Medtronic, Boston Scientific, and Abbott. **Address reprint requests and correspondence:** Dr Hiro Kawata, University of California Irvine Medical Center, 101 The City Dr S, Orange, CA 92868. E-mail address: [hirokawata@hotmail.com](mailto:hirokawata@hotmail.com).

## KEY TEACHING POINTS

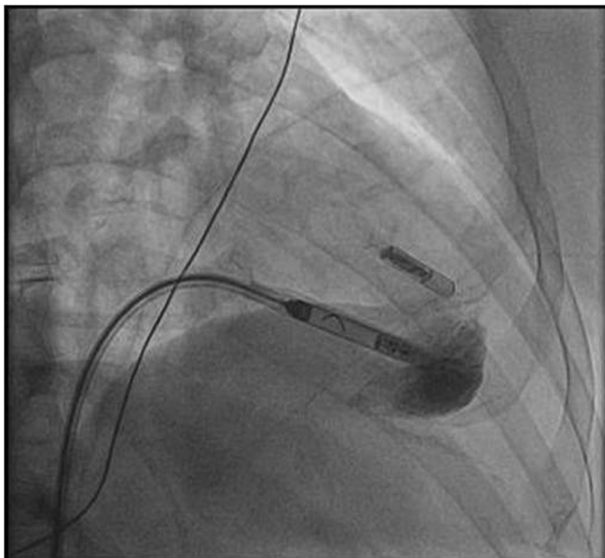
- Compared to conventional pacemaker systems, pacing thresholds in the Nanostim leadless pacemaker showed greater magnitude of improvement of pacing threshold.
- Even if an initial pacing threshold is high, a longer waiting period may lead to significant reduction of the pacing threshold.
- The unique behavior of the Nanostim pacemaker system is likely owing to the difference in the size of the helix and the position of the anode compared to traditional active-fixation transvenous leads.



**Figure 2** Final position of the leadless pacemaker (arrow).

Piccini and colleagues<sup>4</sup> reported on pacing threshold behavior of after implantation of a Micra transcatheter LPS. They confirmed that the pacing threshold of the Micra LPS behaved in a similar fashion to traditional transvenous leads, and the vast majority of patients with a pacing threshold of  $<2$  V had a pacing threshold of  $\leq 1$  V at follow-up. In contrast, patients with a pacing threshold of  $>2$  V had a significant risk of persistently elevated pacing thresholds of  $>2$  V at follow-up. This result suggests that confirmation of low threshold at the initial implant is associated with acceptable pacing threshold during follow-up.

The Nanostim LPS is a new technology for which trends of pacing thresholds are not well elucidated. The Nanostim LPS has a screw-in helix that penetrates into the right ventricular (RV) myocardium. The device also has nylon tines that provide a secondary fixation system. The tip of the electrode has a composite of dexamethasone sodium phosphate that is



**Figure 1** An initial right ventriculogram was used to identify an appropriate implant location.

intended to promote low acute and chronic stimulation thresholds by suppressing the local inflammatory response to a foreign body. In our 2 patients, the initial RV pacing threshold was too high and in fact we had no capture at maximum output. However, these RV leads appeared to be fixed in an ideal position and repositioning was not performed. Thresholds in both cases did not become acceptable until 25 minutes after implantation, and the following day the threshold improved significantly in both patients.

In a pivotal study, the mean sensing and pacing threshold values improved significantly over time, from  $0.82 \pm 0.69$  V at the time of pacemaker implantation to  $0.58 \pm 0.31$  V at 12 months.<sup>5</sup> Unfortunately this pivotal trial of Nanostim LPS did not make mention of acute threshold immediately after implantation, and no predetermined observation period was defined as to when to determine repositioning vs accepting the implant threshold.

In our cases, compared to traditional active-fixation leads in conventional pacemakers, the Nanostim LPS showed a greater magnitude of improvement of pacing threshold after the initial implantation. This is likely owing to the difference in the size of the helix and the position of the anode compared to traditional active-fixation transvenous leads.

In the pivotal study, 29.8% of patients required repositioning of the Nanostim LPS owing to either high pacing threshold or inadequate sensing amplitude.<sup>5</sup> Cardiac perforation is one of the most serious complications after Nanostim LPS implantation, and unnecessary attempts at repositioning can be associated with perforation.<sup>5</sup> In our patients, a plan of waiting up to 30 minutes and monitoring revealed attenuation of thresholds to a favorable level. This enabled us to circumvent unnecessary repositioning. Further studies are needed to confirm our findings.

## Conclusions

The pacing threshold in the Nanostim leadless pacemaker might be high immediately after implantation. A tentative

plan of waiting and monitoring resulted in the attenuation of thresholds to acceptable levels, and such an approach may be required to avoid unnecessary repositioning. More data are needed to conclude if this watchful waiting strategy should be universally applied to Nanostim LPS.

## References

1. de Buitelir M, Kou WH, Schmaltz S, Morady F. Acute changes in pacing threshold and R- or P-wave amplitude during permanent pacemaker implantation. *Am J Cardiol* 1990;65:999–1003.
2. Kistler PM, Kalman JM, Fynn SP, Singarayar S, Roberts-Thomson KC, Lindsay CB, Khong U, Sparks PB, Strathmore N, Mond HG. Rapid decline in acute stimulation thresholds with steroid-eluting active-fixation pacing leads. *Pacing Clin Electrophysiol* 2005;28:903–909.
3. Sekita G, Nakazato Y, Hayashi H, et al. Rapid improvement and long-term stability of pacing threshold with active-fixation screw-in lead. *J Arrhythm* 2010; 26:244–249.
4. Piccini JP, Stromberg K, Jackson KP, et al. Long-term outcomes in leadless Micra transcatheter pacemakers with elevated thresholds at implantation: Results from the Micra Transcatheter Pacing System Global Clinical Trial. *Heart Rhythm* 2017; 14:685–691.
5. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. *N Engl J Med* 2015;373:1125–1135.