

The unstable pacing thresholds of the leadless transcatheter pacemaker affected by body positions in subacute phase after implant

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Background

If the threshold at implant of leadless transcatheter pacemakers (LTPs) is less than 2.0 V, pacing thresholds reportedly decrease significantly by 1 month and maintain an optimal value of less than 1.0 V by 6 months.

Case summary

We report a case series of two patients with unstable pacing thresholds of the LTPs in the subacute phase after implant. The first patient (77-year-old man) was implanted an LTP for sick sinus syndrome. At that time of implant, the pacing threshold was 0.9 V at 0.24 ms. At 1 week and 1 month later, the threshold had increased to more than 2.0 V at 0.24 ms. We investigated the trend data for the week and found variations in the threshold. The second patient (81-year-old man) was implanted an LTP for bradycardia and atrial fibrillation. The pacing threshold at implantation was 0.63 V at 0.24 ms. One week later, the threshold had increased in supine position and decreased in sitting position. The trend data for the week were fluctuating greatly.

Discussion

The pacing threshold may increase to more than 2.0 V with significant fluctuation on assessment at 1 week and 1 month after implantation in association with changes in body position, even though we confirmed a stable threshold at implant. If an increased threshold is observed, it is necessary to check the trend data and threshold in each body position.

Keywords

Leadless pacemaker • Threshold • Body position • Subacute phase • Fluctuation • Case series

Learning points

- The pacing threshold may fluctuate significantly with change in body position in the subacute phase after leadless pacemaker implantation.
- Even if an optimal threshold and confirming stable fixation was obtained at implantation, the pacing threshold could be unstable on assessment at 1 week and 1 month.
- The only clues to an unstable threshold due to change in body position were the trend data after implantation. Therefore, it is important to check the trend data at a later time point.
- Furthermore, if a large fluctuation of the threshold is observed, we should check the pacing threshold according to changes in body position.

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Introduction

Leadless pacemakers were designed to reduce or eliminate the complications related to the subcutaneous pocket or leads that occur with use of traditional transvenous pacemakers.¹ Leadless transcatheter pacemakers (LTPs) reportedly have a high rate of implant success and a low rate of major complications in actual clinical use.² Leadless transcatheter pacemakers have been widely accepted, and have demonstrated long-term safety and efficacy.^{3,4}

Pacing thresholds in most LTPs reportedly decrease if the threshold at implant is less than 2.0 V, and maintain an optimal value of less than 1.0 V by 6 months.⁵

The Micra™ transcatheter leadless pacing system (Medtronic, Inc., Minneapolis, MN, USA) uses four self-expanding nitinol tines to anchor the device to the ventricular myocardium and is thought to be stably fastened with at least two tines in place.

However, we experienced two cases in which the pacing threshold increased to more than 2.0 V at 0.24 ms and showed daily fluctuation on assessment at 1 week and 1 month in association with changes in body position, even though we confirmed fixation with at least two tines and a stable threshold in supine position (less than 1.0 V at 0.24 ms) at implant, 5 min and 10 min after implantation.

Timeline

Case series

Patient 1

A 77-year-old man (body mass index: 21.4 kg/m²) experienced early morning syncope and was admitted to our hospital in November 2017. He was quadriplegic at the time of admission due to a cervical cord injury associated with syncope. After admission, the electrocardiogram revealed sinus arrest (more than 5 s) with junctional escape beats for a brief period every night. Therefore, we implanted an LTP rather than a dual-chamber pacemaker because of his limited physical activity and expected low ventricular pacing rate, under general anaesthesia on Day 7. A 27-Fr delivery sheath was carefully introduced percutaneously after progressive dilatation of the right femoral vein. The LTP was successfully implanted at the first attempt without technical difficulty at the low right ventricular septum. We confirmed fixation of three tines under fluoroscopy. The pacing threshold at implantation was 0.9 V at 0.24 ms, sensitivity was 5.4 mV, and impedance was 520 Ω, with stability maintained at 5 min and 10 min after implantation. When the LTP was interrogated 1 week later, the pacing threshold had increased to 2.25 V at 0.24 ms, and impedance had decreased to 390 Ω. Therefore, we investigated the trend data for the week, and observed significant daily fluctuation of the threshold from 1.25 V to 2.88 V at 0.24 ms (Figure 1A). We confirmed the absence of acute febrile illness during the week of examination [C-reactive protein: 0.5 mg/dL (normal value 0–0.3)] and electrolytes abnormalities [Na: 139 (138–146), K: 3.9 (3.5–5.0), Cl: 108

Patient 1

Pre-implantation	Admission due to a cervical cord injury associated with syncope Sinus arrest (more than 5 s) with junctional escape beats for a brief period every night by the electrocardiogram
Implantation	A leadless transcatheter pacemaker (LTP) was implanted in 2017 The pacing threshold at implantation was 0.9 V at 0.24 ms
1 week later	The pacing threshold had increased to 2.25 V at 0.24 ms The trend data for the week were observed the threshold from 1.25 V to 2.88 V at 0.24 ms Stable LTP position on chest X-ray
1 month later	We found variation in the pacing threshold according to body position (1.13–2.5 V at 0.24 ms) The same result as the data after 1 week

Patient 2

Pre-implantation	Permanent pacemaker was implanted with epicardial leads in 1988 for bradycardia with atrial fibrillation during aortic valve replacement Battery depletion with a significant increase in pacing threshold and resistance at the epicardial leads
Implantation	A LTP was implanted and the old battery was removed in 2018 The pacing threshold at implantation was 0.63 V at 0.24 ms
1 week later	The pacing threshold had increased to 2.38 V at 0.24 ms The trend data for the week were observed the threshold from 0.38 V to 2.5 V at 0.24 ms Stable LTP position on chest X-ray
1 month later	We found variation in the pacing threshold according to body position (0.5–2.38 V at 0.24 ms) The same result as the data after 1 week

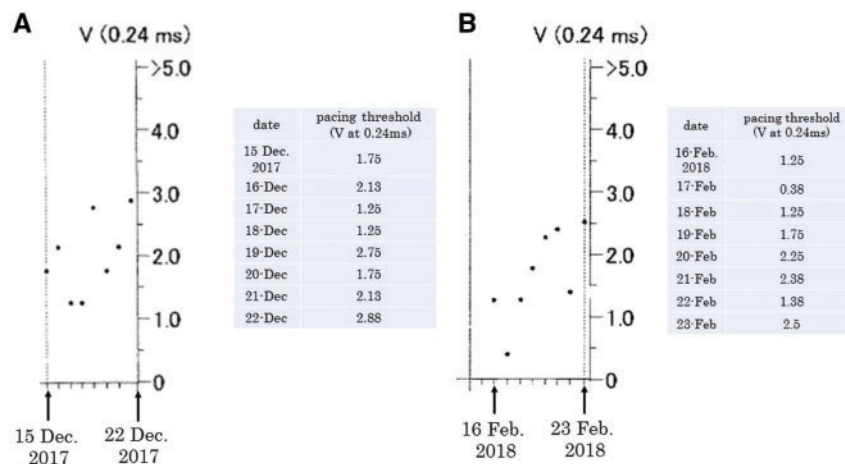


Figure 1 The trend data for the week after implantation of case. (A) Case 1 and (B) Case 2; large daily fluctuation of the threshold was observed.

(100–110 mEq/L] and stable LTP position on chest X-ray (Figure 2A) at that point. We also found variation in the pacing threshold according to body position, with the lowest value of 1.13 V at 0.24 ms in the left lateral decubitus position and the highest value of 2.5 V at 0.24 ms in sitting position (Table 1). Impedance did not change with body position, and remained between 430 Ω and 460 Ω . We again measured the pacing threshold in different body positions 1 month later and observed the same results.

Patient 2

An 81-year-old man (body mass index: 22.9 kg/m²) underwent permanent pacemaker implantation with epicardial leads in 1988 for atrial fibrillation with bradycardia during aortic valve replacement. At our outpatient clinic, we observed battery depletion, with a significant increase in pacing threshold and resistance at the epicardial leads. Due to mobility limitations due to knee joint pain, the patient had restricted mobility. Therefore, we implanted an LTP and removed the old battery in February. The LTP was successfully implanted at the first attempt without any technical difficulty at the mid-right ventricular septum. We confirmed fixation of three tines under fluoroscopy. The pacing threshold at implantation in supine position was 0.63 V at 0.24 ms, sensitivity was 4.4 mV, and impedance was 510 Ω , with stability maintained at 5 min and 10 min after implantation. When the device was interrogated 1 week later, the pacing threshold had increased to 2.38 V at 0.24 ms, and impedance had decreased to 370 Ω in supine position. We investigated the trend data for the week and observed significant daily fluctuation of the threshold from 0.38 V to 2.5 V at 0.24 ms (Figure 1B). We confirmed the absence of acute febrile illness during the week of examination (C-reactive protein: 0.6 mg/dL) and electrolytes abnormalities (Na: 139, K: 4.2, and Cl: 108 mEq/L) and stable LTP position on chest X-ray (Figure 2B) at this point. We also found variation in pacing threshold according to body position, with the lowest value of 0.5 V at 0.24 ms in sitting position and the highest value of 2.38 V at 0.24 ms in supine position (Table 1). Impedance did not change with body position, and remained between 370 Ω and 400 Ω . We again measured the pacing

threshold in different body positions 1 month later and observed the same results.

Discussion

The major finding in these cases was the increased pacing threshold to more than 2.0 V at 0.24 ms, with significant fluctuation on assessment at 1 week and 1 month after implantation in association with changes in body position, even though we confirmed fixation with at least two tines and a stable threshold in supine position (less than 1.0 V at 0.24 ms) at implant, 5 min and 10 min after implantation.

To the best of our knowledge, this is the first report of fluctuating thresholds in association with changes in body position in the sub-acute phase after LTP implantation.

An LTP is generally implanted in supine position and telemetry data are usually obtained in supine position at implantation, as well as 1 week and 1 month later. Reports have shown that available pacing thresholds at implantation remained nearly stable at 12 months and 24 months of follow-up.^{3,4} If the threshold is >2.0 V at 0.24 ms at implantation, Piccini *et al.*⁵ recommended that clinicians should strongly consider recapturing and redeploying the device, since a pacing threshold of >2.0 V at implantation was associated with high capture thresholds in almost half of all patients at 6 months. In our cases, an optimal threshold was observed at implantation, but increased to >2.0 V, with reduced impedance 1 week later. The threshold trend data for 1 week showed large daily fluctuations. We, therefore, measured thresholds in supine, left lateral decubitus, right lateral decubitus, and sitting positions, and confirmed large fluctuations in pacing threshold in association with changes in body position. Moreover, we confirmed similar changes after 1 month.

The LTP manufacturer reported that, compared with the tine holding energy at dislodgement, there was an estimated 79 times tine holding energy at rest, and a 15 times energy during exercise conditions for two tines engaged in tissue⁶ and recommends confirming stable fixation with at least two out of four tines, confirmed with a tug test during implantation under fluoroscopy. In our cases, we

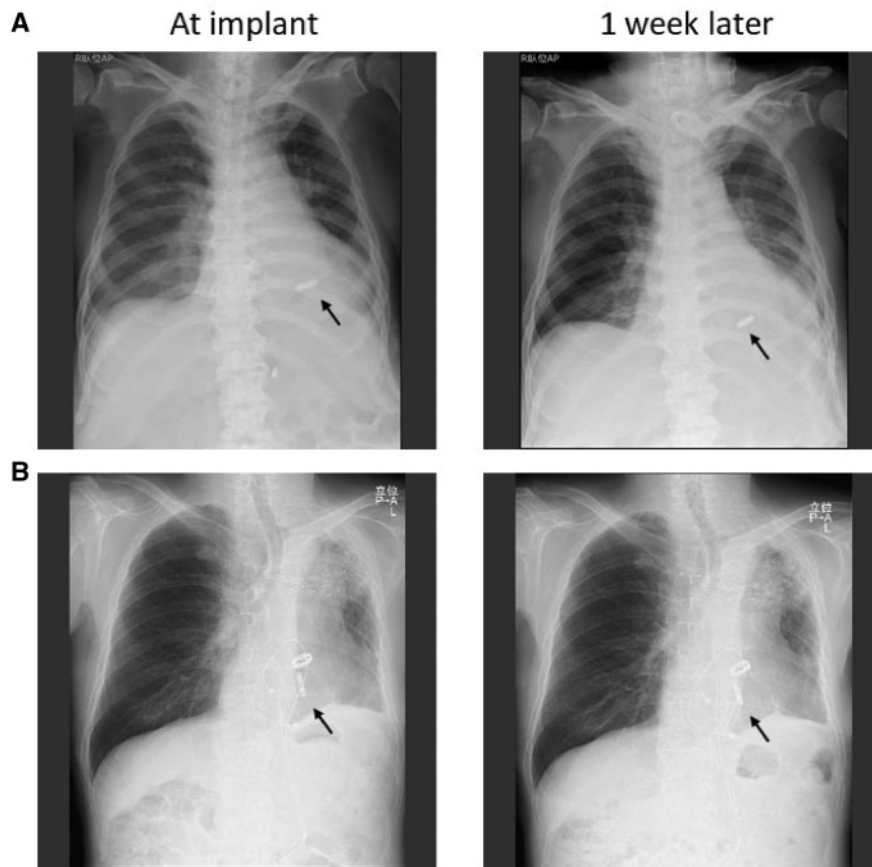


Figure 2 Leadless transcatheter pacemaker position on chest X-ray. (A) Case 1 and (B) Case 2; leadless transcatheter pacemaker position was stable at implant and 1 week later in both cases. An arrow shows leadless transcatheter pacemaker.

confirmed that three tines were fixed to the myocardium at the mid-right ventricular septum, with a stable pacing threshold, sensitivity, and impedance at implantation. Although we compared these settings, the number of fixed tines, and the implantation sites in patients with and without fluctuating thresholds, we found no differences. Therefore, we did not anticipate finding fluctuating thresholds in association with changes in body position. Accordingly, fixation with at least two tines, as the manufacturer recommends, may be insufficient. There are a couple of similar cases local manufacturer engineers have experienced, but the cause of unstable threshold in association with changes in body position is still unknown. The fluctuating thresholds in association with changing position mean unstable fixation of LTP to myocardium. In our cases, some of the tines might be fixed to superficial septum or not only septal myocardium but also the moderator band. Due to the unstable fixation and wide space at the mid-right ventricle, we speculated the LTPs might show fluctuating thresholds in association with changing position. We have implanted the LTP in apical septum and confirmed the fixation of at least three tines to septal myocardium by intracardiac echocardiography since these two cases. In our cases, the only clues to an unstable threshold were the trend data after implantation. Even though an optimal threshold is

observed at implantation, it may be necessary to check the trend data at a later time point. The difference between the highest and lowest pacing threshold in Case 1 is smaller than Case 2. We speculated the difference might be related to the severe limitation of the physical capacity in Case 1.

In our cases, the pacing threshold had increased on assessment 1 week and 1 month later, but was still <2.5 V, even though an optimal threshold was obtained at implantation. This threshold was thought to be acceptable, without the need to retrieve the device. Duray et al.³ evaluated long-term performance and found that pacing thresholds tended to decrease after implantation and remained stable for up to 24 months thereafter. Therefore, we did not retrieve the devices in these two patients, with the expectation that fixation might stabilize and that the pacing threshold might decrease in the near future. Actually, the pacing threshold in the Patient 2 was the lowest value of 1.0 V at 0.24 ms in the sitting position and the highest value of 1.5 V at 0.24 ms in the left lateral decubitus position at 3 months later. The pacing threshold decreased and the difference between the highest and lowest pacing threshold became smaller at 3 months after implant in this case. For the Patient 1, we did not have data at 3 months later because he died due to aspiration pneumonia

Table 1 Telemetry data in different body positions

	At implant	5 min later	10 min later	7 days later	1 month later
Case 1					
Pacing threshold (V)					
Body position					
Supine	0.9	0.9	0.9	2.25	1.63
Left lateral decubitus				1.13	1.5
Right lateral decubitus				2.13	1.75
Sitting				2.5	2
Sensitivity (mV)					
Supine	5.4	5.2	5.4	7	6.8
Left lateral decubitus				8.3	7
Right lateral decubitus				6.4	6.4
Sitting				7.2	5.3
Impedance (Ω)					
Supine	520	480	520	450	430
Left lateral decubitus				460	430
Right lateral decubitus				450	440
Sitting				430	430
Case 2					
Pacing threshold (V)					
Body position					
Supine	0.63	0.63	0.63	2.38	2.25
Left lateral decubitus				2	1.88
Right lateral decubitus				1.38	1.38
Sitting				0.5	0.88
Sensitivity (mV)					
Supine	4.4	4.4	4.4	NA	NA
Left lateral decubitus				NA	NA
Right lateral decubitus				NA	NA
Sitting				NA	NA
Impedance (Ω)					
Supine	510	530	510	370	420
Left lateral decubitus				370	420
Right lateral decubitus				380	430
Sitting				400	420

NA, not available due to complete atrioventricular block.

at 2 months later, which was not related to LTP implantation. We will carefully monitor the pacing threshold in various body positions in these patients. We showed only two cases and it was difficult to make a strong conclusion. So we need for more studies in this regard.

Conclusion

The pacing threshold may fluctuate significantly with changes in body position in the subacute phase after implantation. Even if an optimal threshold is observed at implantation, it may be necessary to check the trend data at a later time point. If a large fluctuation is observed, it may be necessary to monitor changes according to changes in body position.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as [Supplementary data](#).

Consent: The authors confirm that written consent for submission and publication of this case series including image(s) and associated text has been obtained from the patients in line with COPE guidance.

Conflict of interest: none declared.

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