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Management of a leadless pacemaker recall via extraction in a patient with a history of multiple previous device implants

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ABSTRACT

We describe a management strategy of a leadless pacemaker recall (LP) via extraction in a pacemaker-dependent patient with a history of multiple previous device implants. We performed a two-step procedure. First, we implanted a second LP in the right ventricle. Then, 3 days later for concerns about the stability of the newly-implanted device, we retrieved the first LP, 3 years after its original implant. The patient was hemodynamically stable throughout the two procedures and no adverse event occurred in the 3 days of coexistence of the two LPs. Although the limitation of a single case experience, this approach may be taken into consideration when facing similar high-risk cases.

Introduction

Leadless pacemaker (LP) can be considered as a safe and effective alternative to traditional pacemakers, as they can avoid lead and pocket-related complications [1,2].

Two different leadless pacing systems have been developed and launched on the market. The first device has been the Nanostim™ LP (St. Jude Medical [now Abbott], Sylmar, California, USA). Few years later, Medtronic, Inc. (Minneapolis, MN, USA) released the Micra™ Transcatheter Pacing System.

Despite LP represents a breakthrough technology in the electrophysiology area, these devices are not free from risks of malfunction or design faults. Following events of battery malfunction resulting in loss of telemetry and pacing output, St. Jude Medical decided to suspend Nanostim™ implants on October 2016. Immediate device replacement was recommended in pacemaker-dependent patients.

This case report describes a management strategy of a LP recall in a pacemaker-dependent patient with a history of multiple previous infections of conventional transvenous systems.

Case report

We present the case of an 80-year-old male patient suffering from a 3rd degree atrioventricular block and implanted in January 2014 with a Nanostim™ LP. The patient had stable ischemic cardiomyopathy, diabetes mellitus type II and arterial hypertension. Previously he was implanted with two conventional transvenous pacing systems. The first dual-chamber PM was implanted in 1999 (upper left chest side). In December 2013, the system was entirely removed due to a systemic infection via a transvenous extraction procedure that required the use of both laser-powered (Spectranetics CVX-300 40–80 Hz, The Spectranetics Corporation, Colorado Springs, CO USA) and mechanical extraction sheaths (Cook Medical Inc., Bloomington, IN USA). Subsequently, the patient received a new dual-chamber PM system (upper right chest side implant) that was removed in January 2014 via simple manual traction due to a new episode of endocarditis and positive blood culture of Staphylococcus Pseudintermedius.

Because of the multiple episodes of endocarditis, we decided to implant a Nanostim™ LP. The procedure was performed in our Electrophysiology Laboratory (EP) without any complication. The next two years were free from clinical adverse events and device deficiencies. After the official recall of the device, we decided to replace the Nanostim LP with the new Micra™ LP due to the patient's pacemaker-dependent status and his history of multiple previous infections of conventional transvenous systems.

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The procedure was performed in our EP Lab with a continuous 12-lead electrocardiogram and arterial blood pressure monitoring. Transthoracic echocardiography excluded structural baseline heart diseases and was repeated during all crucial steps of the procedure. Inferior vena cava patency and absence of tortuosity were confirmed through venography. The implant of the Micra™ device was successfully performed according to the technique widely described in the literature (Fig. 1A) [3]. The newly-implanted system was placed as far as possible from the Nanostim™ LP (Fig. 1B). The pacing mode of the Micra™ device was set in VVIR with a basic rate of 60 beats/min, while the Nanostim™ was set in VVI at a lower basic rate (30 beats/min). For the next 3 days, the patient remained hospitalized and monitored with telemetry. No interferences or malfunctions were detected on the ECG or at the interrogation of the two implanted LPs.

The Nanostim™ was then extracted. The patient was prepared according to our standard protocol as described for the LP implantation and with a cardiothoracic surgery standby. The Nanostim™ Retrieval Catheter (St. Jude Medical [now Abbott], Sylmar, California, USA) was advanced under fluoroscopic guidance via the right femoral route to the right atrium. The deflectable single-loop snare tip was then advanced just behind the Nanostim™ LP (Fig. 1C). Once the pacing system was hooked, it was completely detached from the ventricle endocardium by rotating the device two times. Eventually it was retracted inside the protective sleeve and extracted through the femoral vein introducer (Fig. 1D). The patient was hemodynamically stable throughout the procedure. The final angiography confirmed cardiac integrity and the echocardiographic check excluded pericardial effusion. Despite roughly 3 years of implantation, the extracted LP did not show significant fibrosis (Fig. 2).

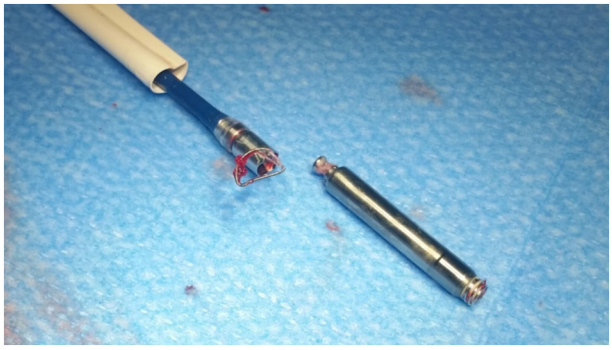

Fig. 2. The Nanostim™ leadless pacemaker after retrieval did not show significant fibrosis.

Discussion

The implant of a LP is an alternative option to the use of conventional cardiac pacing system, with potential benefits in terms of reduction of complications related to the subcutaneous pocket and transvenous leads.

However, little is known about extraction of LP. Some cases are reported in literature covering different reasons for device replacement and with different outcomes [4–6].

Reddy et al. reported a complete extraction in 91% of patients with Nanostim™ implanted for around 1 year [4]. Recently, Lakkireddy et al. confirmed this data showing a successful extraction rate of 90% on a total of 73 retrieval attempts [5]. In our case, although the removal of the LP was performed in a chronic stage roughly 3 years post implant,

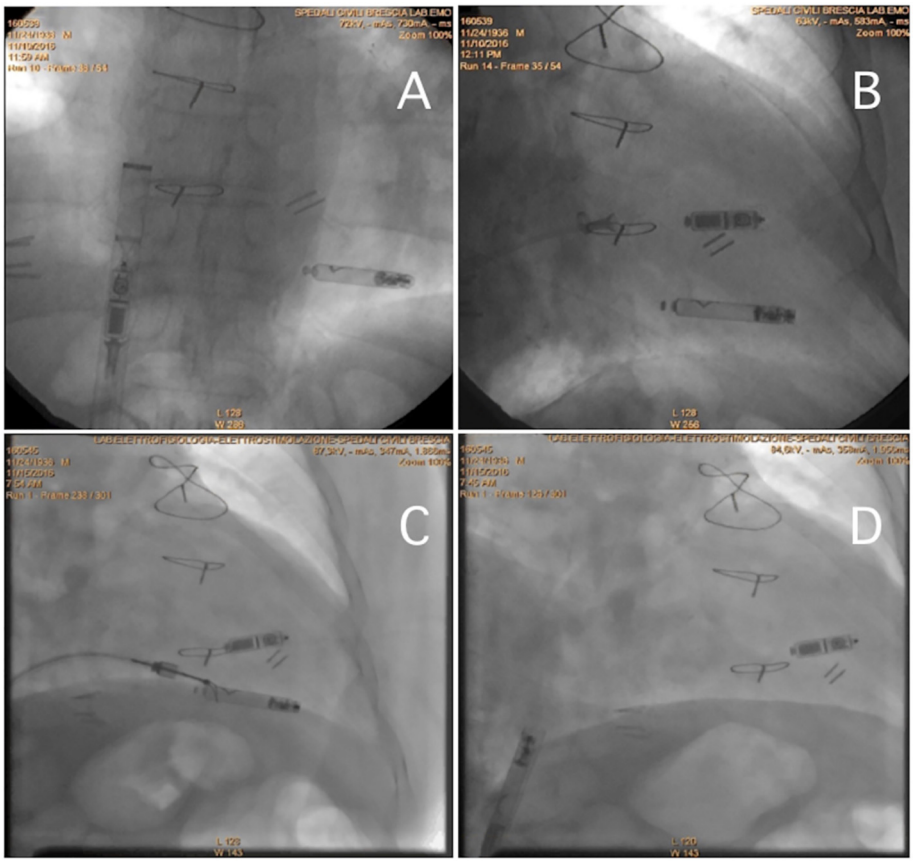

Fig. 1. Micra™ implant and Nanostim™ extraction procedure. Micra delivery system was advanced within the dilator in the right atrium (Panel A). The newly-implanted system was placed as far as possible from the Nanostim™ (Panel B). Three days later, the Nanostim™ was extracted. The device was hooked with a retrieval catheter (Panel C) and, by rotating the screw-in helix, was completely removed (Panel D).

the extracted LP did not show significant fibrosis. This finding seems to supports the feasibility of the extraction procedure even after a relatively long time post-implant, as shown also in animal studies after 24 months [7].

This report represents a challenging case of LP recall management in pacemaker-dependent patient. Because of the history of multiple episodes of endocarditis, the risk of a conventional transvenous implant was deemed too high and an epicardial lead implantation was not considered an appropriate option due to the patient's history of cardiac surgery. Therefore, we decided to implant a second LP in the right ventricle in coexistence with the previous device before proceeding with its extraction. The 3-day "wait period" in between the new device implant and previous device extraction was applied due to concerns about the stability of the newly-implanted system considering the pacemaker-dependent status. Of note, neither mechanical nor functional reciprocal interferences were detected in the coexistence period of the two devices. Recently, multiple LPs implantations in the right ventricle were tested in a swine model study and appeared safe and without significant changes in the cardiac function [8].

Conclusions

We managed a LP recall via extraction in pacemaker-dependent patient with a history of multiple previous device-related infections with a two-step procedure. First, we implanted a second LP in the right ventricle and, 3 days later, we extracted the malfunctioning LP. Although the limitation of a single case experience, this approach may be taken into consideration when facing similar high-risk cases.

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