Retrieval and replacement feasibility of 7-year-old implanted leadless pacemaker with tines fixation

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Introduction

The Micra™ transcatheter pacing system (TPS) (Medtronic, Minneapolis, MN) is a clinically effective alternative to transvenous pacemakers for single-chamber ventricular pacing.[1] Although abandonment of the TPS at the end of life is recommended, retrievability is one of the critical management strategies in specific scenarios.[2] There are no studies pertaining to the safety and feasibility of retrieving and replacing a chronically implanted Micra TPS.[3] Despite already published results, the ability to retrieve or remove a chronically implanted leadless pacemaker (LP), specifically with the anchor fixation type, is an unanswered important aspect of this device management.[4,5] There are only limited experiences available. Moreover, the retrieval procedure itself could be very different for existing systems, for example Micra TPS; Empower™ (Boston Scientific, St. Paul, MN), with 4 metallic tines; or Nanostim™ LCP / Aveir™ (St. Jude Medical/Abbott, St. Paul, MN), with screw-in spiral. For Nanostim/Aveir LCP, a dedicated system for retrieval exists.[4–6] There are 2 options, a single- or triple-loop extraction tool set[6]; for Micra TPS no such retrieval device for extraction was designed. We report the case report of Micra TPS extraction 2.657 days after first implantation.

Case report

In a 78-year-old man with a body mass index of 21.6 kg/m^2 and 10-year history of coronary artery disease after acute anterior wall myocardial infarction, direct coronary artery revascularization was performed with implantation of 2 DES stents in the proximal left anterior descending artery. Left ventricle systolic function was preserved with left ventricular ejection fraction 60% after intervention. Since the myocardial infarction there was evidence of long-standing persistent atrial fibrillation, CHA_2DS_2Vasc score 3, being treated with apixaban 5 mg twice daily. Owing to slow ventricular response during atrial fibrillation and significant asystolic pauses up to 6 seconds, a single-chamber right ventricle (RV) pacemaker was indicated.

A Micra TPS was implanted as part of the IDE clinical trial, without any complications, on December 19, 2014. At implant RV pacing threshold was 1.2 V / 0.24 ms, R-wave sensing amplitude 17.4 mV, and impedance 640 Ω. Two weeks after implantation clinical improvement was reached, with diminishing of dyspnea and fatigue. During subsequent follow-ups over the years there was evidence of a gradual increase in pacing thresholds up to 2.5 V / 0.24 ms. Total percentage of RV pacing reached 63.2%. During the last examination in pacemaker clinic estimated pacemaker end of life was minimum 2 and maximum 6 months. Immediate exchange of the TPS was indicated. Because of moderate anemia related to prolonged treatment with non–vitamin K antagonist oral anticoagulants (apixaban 5 mg twice a day), mechanical left atrium appendage closure was considered as an optional additive treatment. There was a patient request to retrieve the old LP device.

The index retrieval procedure and new Micra TPS implantation were done on March 29, 2022, 2657 days after first TPS implantation.

KEY TEACHING POINTS

- There are valuable indications for leadless system retrievals.
- Chronically implanted Micra transcatheter pacing system can be retrieved safely.
- Reimplantation of a new leadless cardiac pacing device immediately after retrieval of the old one is a safe and feasible strategy.

Description of the procedure

After right femoral venous puncture, a standard 23F Micra sheath was introduced. Before insertion of the delivery catheter for the Micra TPS, we cut the tether and also removed the

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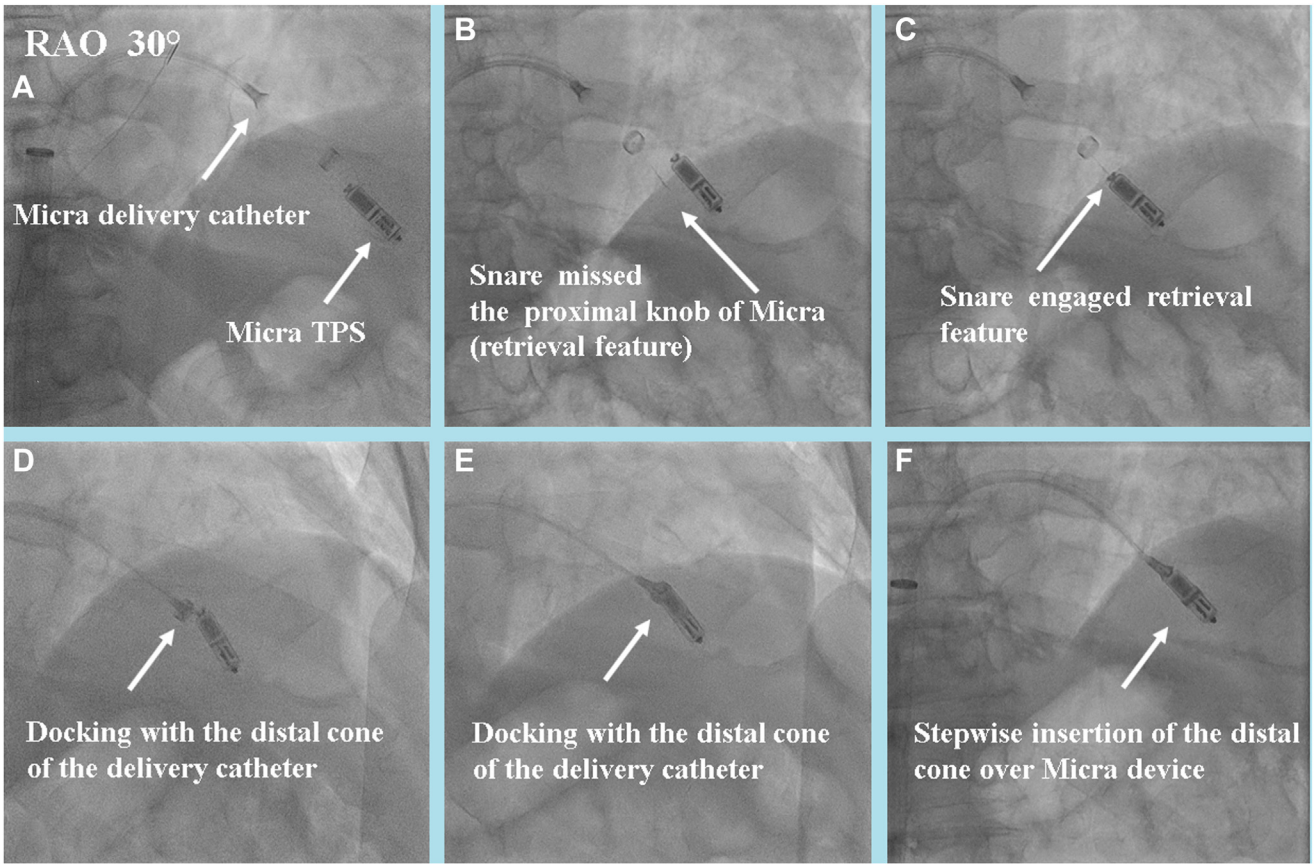

Figure 1 Fluoroscopic images in RAO 30°: **A:** Micra (Medtronic, Minneapolis, MN) delivery catheter introduction to right ventricle chamber with single-loop snare in the middle part of its shaft. **B–F:** Detachment of the proximal docking button of Micra device with the snare (**B,C**) and docking and step-by-step introduction of distal cone of the delivery catheter over Micra device up to the insertion in the tissue (**D,E,F**).

original device from the package. Through the central lumen of the delivery catheter a single snare-loop 7 mm catheter (Amplatz Goose Neck; ev3 Inc, Plymouth, MN) was inserted (Figure 1A). Under fluoroscopy with the guidance of intracardiac echocardiography (ICE), after several attempts we successfully snared the proximal insertion knob (Figure 1B and 1C) and tightly connected the distal hub of the delivery catheter to the old Micra body. With slight force, the operator was able to place the cover cap of the delivery catheter near to the LP RV wall insertion (Figure 1D–1F). Up to this point the operator did not apply any strong force. When the distal edge (visible under fluoroscopy) was in contact with the endocardium, the operator applied counter-traction force. Under fluoroscopy we could control slow movements of all insertion tines, changing their geometry, and then pulled out all insertion tines inside the delivery cup. When the tines were covered by the cup, the old Micra TPS was freed from the RV wall and successfully removed from the patient's body (Figure 2A–2D). Immediate reimplantation of a new Micra TPS through the same Micra 23F sheath into the RV apicoseptal area was achieved, with excellent pacing parameters: RV sensing 12.8 mV, impedance 690 Ω, threshold 0.25 V / 0.24 ms (Figure 2E and 2F). Total procedure time was 45 minutes; total fluoroscopy time was 5 minutes. There were no significant signs of tissue on preprocedure ICE recording and on the retracted device itself (Figure 3A–3C). The patient was discharged the next day and during follow-ups the stable pacing parameters were confirmed.

Discussion

This case report demonstrates retrieval of LP Micra TPS as a feasible procedure several years after its implantation. Considering different active fixation mechanism comparing the other type of LP fixation (helix), this case report, based on our previous single-center experiences,[7] indicates several aspects: (1) after a long period since implantation, the Micra device could be retractable with an existing delivery catheter adapted with a single-snare catheter; (2) despite that all 4 tines were tightly connected to the tissue, with force and adapting counter-traction we were able to release the LP from the site of insertion; (3) the critical part of the procedure is to properly snare the fixation knob of the LP device and free the body from potential tissue overgrowth; and (4) the new Micra TPS device showed excellent parameters in a slightly different insertion site.

The acute LP retrieval success rate is high—reports are about early post–implantation procedure retrieval—but we need to be ensure what to do when elective replacement of

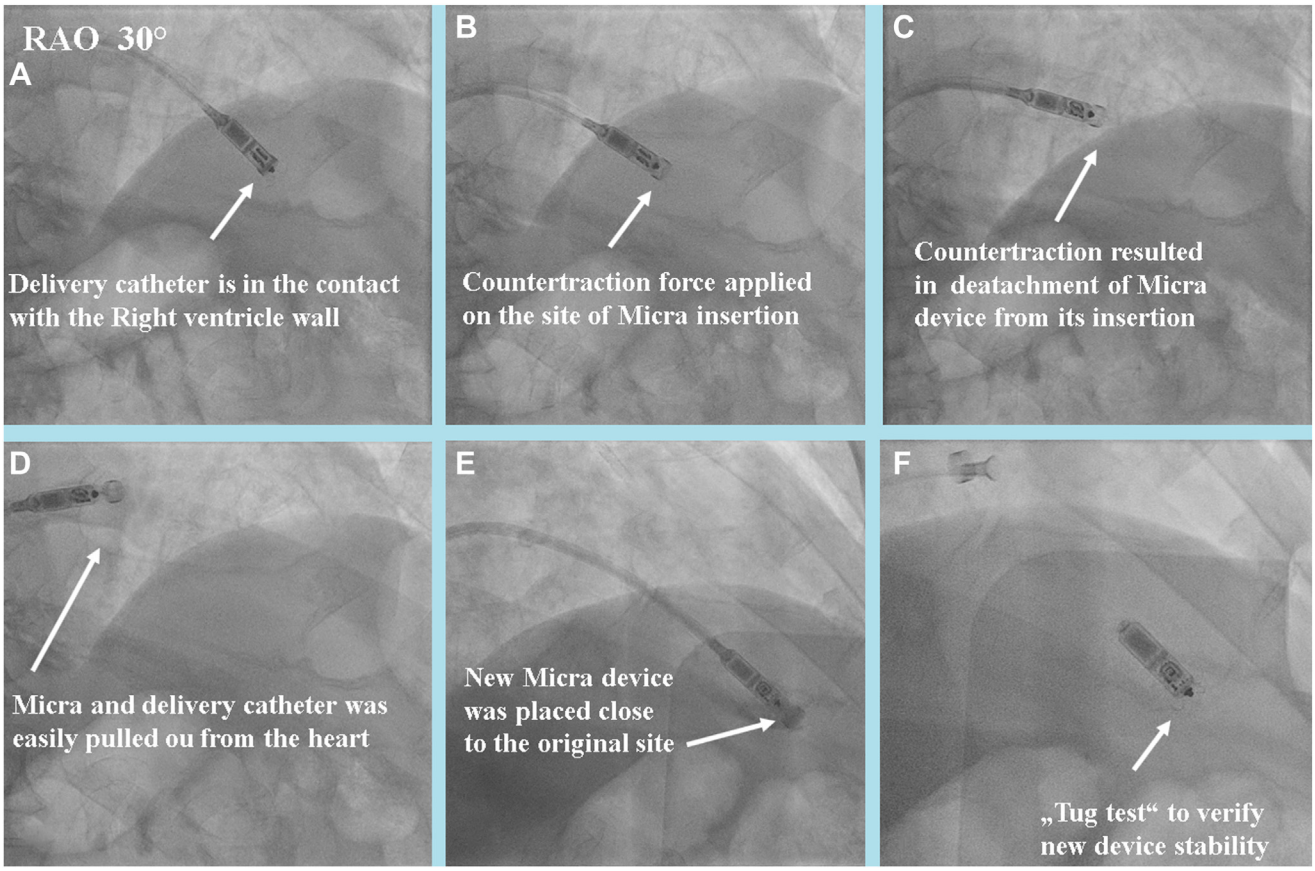

Figure 2 **A–D:** Fluoroscopic views in RAO 30° with fully inserted delivery catheter cone over the Micra (Medtronic, Minneapolis, MN) device (**A**), followed by counter-traction (**B**) and free manual traction (**C,D**) to disengage the tip of the Micra device from the endocardium. **E, F:** New Micra device is being implanted immediately after old device retrieval in similar site of insertion.

LP is indicated.[8] LPs represent a new challenge, since the device and electrode is a unique component; some experts thought we can implant only old patients with limited life expectancy, to insert only 1 or a maximum of 2 devices per patient life.[4] With a very small container (volume: 0.75 cc; mass: 2 g; length: 24 mm; width: 20F) the LP lends itself to a strategy of simply abandoning the old device or devices and placing an additional LP.[3] When dedicated extraction tool sets are developed, it might lead to safe removal of the majority of already implanted LPs.[9] Despite that the average age of patients in the Micra worldwide study was 75.9 ± 10.9 years,[1] there is a significant percentage of much younger patients, and with expected battery longevity around 10 years we must consider designed exchangeable LP devices in the near future. Moreover, abandoning devices may be a less practical practice, not only in younger patients but in those with smaller a RV chamber. There remains the possibility of an LP infection, which may require device removal to achieve bloodstream clearance.[10]

Likewise, regarding standard transvenous pacemaker leads, we need to wait for data from our own clinical practice. This research (LP retrieval) could not be done by prospective trial while only few patients reach more than 1 or 2 years after implantation. There are individual case reports of successful retrieval of Nanostim LCP with screw-in fixation, which indicated a safe and effective way to retrieve these LP devices,[11] but that experience represents that different fixation mechanisms can also determine specific retrieval tools we need to develop.[6] There are increasing data suggesting that this device removal is feasible even after more than 2 years.[12] For Nanostim LP devices we proved the potential for successful retrieval while, owing to the free “swinging” movement under fluoroscopy or ICE, we predict better outcomes of the retrieval procedure.[7] The Micra TPS uses a 4-tine active-fixation mechanism, which in theory limits success in its removal from the tissue insertion; commercially designed tools are still missing. The manufacturer recommends to use the Agilis deflectable catheter (Abbott Inc, St. Paul, MN) but it is not predisposed to use real counter-traction. As well as for Nanostim LCP and Micra TPS, encapsulation with the tissue can occur and can critically limit the feasibility for extraction; at the same time we need a similar system for dissection of the tissue around the device capsule while we cannot predict a degree of encapsulation. When docking of the extraction catheter tool and the LP device is tight, there is high potential for applying much more effective counter-traction from a transfemoral approach.[13] There is unpublished data from the manufacturer’s FDA submission on percutaneous removal of the Micra TPS, but systematic published data on the extraction of chronically implanted Micra TPS are still missing. As compared to transvenous lead extraction, we can eliminate the most life-threatening

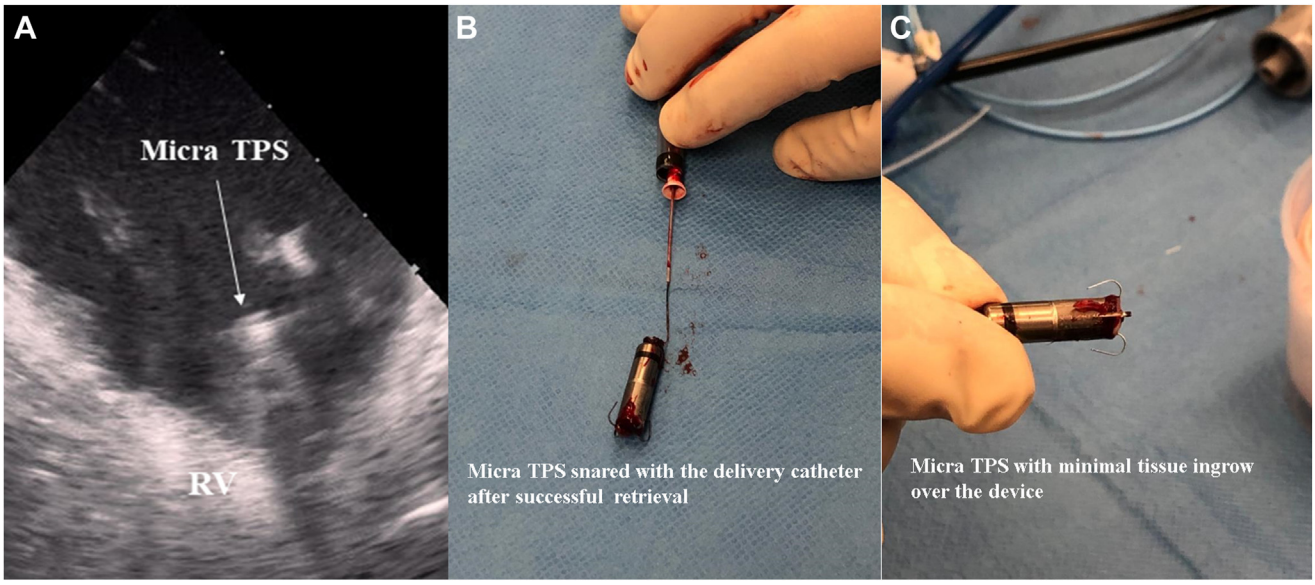

Figure 3 **A:** Intracardiac echocardiography focused on right ventricle (RV). Arrow indicates no any tissue ingrown on the docking button and proximal part of Micra (Medtronic, Minneapolis, MN) device. **B, C:** Images of extracted Micra leadless pacemakers demonstrating nice attachment of the single-loop snare over the docking button (**B**) and minimum amount of fibrosis over the device after 2657 days since implant (**C**).

complication during the procedure, which we consider to be rupture of the superior vena cava venous wall, but on the other hand when cardiac wall perforation happens it can result in massive life-threatening bleeding into the pericardial space. Therefore we strongly recommend to perform this chronically implanted LP extraction in the hybrid room under ICE control, oxygen saturation, brain oxygen saturation, and intra-arterial blood pressure measurement, with a cardiac surgeon's team standing by.

Conclusion

Micra TPS can be safely retrieved up to 8 years after its implantation. This manuscript is the first to describe a feasible procedure.[14,15]

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