How to Implant a Leadless Pacemaker With a Tine-Based Fixation

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Leadless Implant Procedure. Two major studies have shown that leadless pacemakers are safe and effective for patients requiring right ventricular rate responsive pacing therapy. This positive result recently led to FDA approval of one of the available leadless pacing devices. While this new technology is promising, it requires a different skill set for safe implantation. In this article, we review in detail the different steps required for implantation of tine-based leadless pacemakers while providing tips and tricks to minimize complications. (J Cardiovasc Electrophysiol, Vol. 27, pp. 1495-1501, December 2016)

leadless pacemaker, Micra, Nanostim, transvenous pacemaker

Introduction

Implantable pacemakers have evolved remarkably over the last 50 years, from a relatively primitive system to a sophisticated multi-chamber system with complex and refined circuitry.1 As safe and reliable as these devices are today, the pacemaker pocket and lead remain responsible for a significant percentage of short- and long-term complications seen with traditional transvenous pacemakers.3,4 Lead complications include but are not limited to dislodgement, fracture, and infection.3,4 Pocket complications such as hematoma, infection, and dehiscence are also commonly encountered with traditional pacing systems.3,4 Leadless pacemakers (LP) were designed to eliminate lead and pocket-related complications commonly encountered with traditional pacemakers.5,6 The Medtronic IDE trial reported more than 700 patients successfully implanted with the Micra transcatheter pacemaker.5 In this trial, the Micra system had 51% fewer complications as compared to a historical cohort of more than 2,600 patients implanted with a traditional transvenous pacing system. These encouraging results recently led to FDA approval.

Also, the Leadless II study evaluated the St. Jude Nanostim system.7 This trial enrolled more than 500 patients and showed similarly an excellent implant success rate (95.8%) and low complication rate (6.7%).

One of the primary differences between the 2 LP (Table 1) is the fixation mechanism. While the Micra device has a tine-based fixation mechanism, the Nanostim has a screw-in helix fixation mechanism.

Additionally, Boston Scientific is developing a third LP,8 which is also a tine-based device.

While this manuscript will not focus on implantation of LP with a screw in fixation mechanism, some similarities exist in the implantation process: specifically, femoral access and advancement of a large bore delivery system into the RA and across the tricuspid valve, and maintaining connection of the device with a tether like mechanism. There are, however, major differences in the handling of the delivery tool, fixation of the device, recapturing and repositioning of the device if needed.

For example, the tine-based fixation is activated by simply retracting the delivery tool to release the tines with adequate tip pressure, while the helix-based fixation requires a tool to create torque to twist the helix into the tissue without over torqueing and coring the tissue. The implantation of the other tine-based device may show more similarities to the implantation of the Micra; however, human experience is still needed.

This new, innovative technology requires a specialized skill set for implantation, including expertise with large bore sheaths and manipulation of a large delivery system in the right atrium (RA) and right ventricle (RV). In this report, we present the technical and procedural aspects of implanting a tine-based LP specifically focusing on the Micra TPS pacemaker (the only commercially available tine-based pacemaker).
TABLE 1
Difference Between Nanostim and Micra

|                | Nanostim | Micra  |
|----------------|----------|--------|
| Length (mm)    | ≈ 41     | ≈ 26   |
| Diameter (mm)  | 5.33     | 6.67   |
| Volume (cm³)   | 1        | 0.8    |
| Weight (g)     | 2        | 2      |
| Fixation mechanism | Helical | Tissue engaging tines |
| Sensor         | Temperature | Accelerometer |

Adapted and Modified from Sperzel et al.16

Figure 1. A: Micra introducer. B: Micra delivery system. C: Micra device. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology’s website: www.wileyonlinelibrary.com/journal/jce

Implant Procedure and Technique

The procedure consists of 7 steps:

1. Venous access and positioning the introducer
2. Guiding the delivery system to the RV
3. Deploying the device
4. Testing the device
   a) Pull and hold test
   b) Electricals
5. Recapture and reposition (if required)
6. Removing the tether
7. Removing the introducer and obtaining hemostasis

Venous Access and Positioning the Introducer

The Micra introducer system is a 23-French sheath with a hydrophilic coating, which needs to be activated by sodium chloride solution or water before insertion.

Given the size and anatomical variation of the femoral arterial and venous circulation,11 it is worth considering the use of ultrasound-facilitated access to avoid inadvertent femoral arterial puncture and minimize groin complications.

Ultrasound has been accepted as the standard of care for superior access of the jugular venous system for monitoring and administration of drugs centrally. Venous access of the femoral arterial and venous system has traditionally not used ultrasound in the field of cardiology, yet in interventional radiology it is routine. Venous access complications are likely to be compounded in the Micra system due to the large diameter of the introducer sheath. The authors

in crossing the tricuspid valve. The actual pacemaker is a “capsule” like device8,10 weighing 2 grams with a volume of 0.8 cc. Micra has a unique fixation mechanism that is composed of 4 nitinol tines that allow the device to fixate to the myocardium. With this fixation system there have been no reported dislodgements in the IDE trial.5 The cathode electrode is at the distal tip of the capsule and the anode is a ring around the proximal portion of the capsule (Fig. 1C). The Micra is “tethered” to the delivery system during the procedure and then cut once the device is positioned in its final implant location.

TABLE 2
Potential Hurdles During Implant and Troubleshooting

| Difficulty         | Encountered Problem                                      | Solution                                      |
|--------------------|-----------------------------------------------------------|-----------------------------------------------|
| Access             | - Resistance at Skin Level                                | - Large Skin Nick                             |
|                    | - Resistance at Venous Entry                              | - Serial Dilation                             |
|                    | - Resistance at Iliac Bifurcation                          | - Perform Venogram, Consider Switching to Left Femoral Vein |
| Crossing the TV    | - Difficulty Crossing the TV                               | - Start Lower in the RA                       |
| Poor Fixation      | - Inability to get adequate attachment to the myocardium  | - Maneuver the catheter in RAO                |
| Poor Electricals   | - Poor thresholds and sensing                             | - Advance delivery catheter further until it has a swan neck appearance |
|                    | - Elevated Impedance                                      | - Inject contrast to confirm good contact with endocardium |

Figure 1. A: Micra introducer. B: Micra delivery system. C: Micra device. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology’s website: www.wileyonlinelibrary.com/journal/jce
postulate that a central puncture of the femoral vein is less likely to result in tear or laceration of the vein when the sheath is introduced over a guide wire (Fig. S1). Ultrasound allows for the evaluation of the anatomy of the femoral region providing accurate documentation of the relative location of the femoral artery and its branches compared to the femoral vein. It is not unusual for the femoral vein to lie deep to the artery at some stage in its course (Fig. S2). The venous and arterial structures are easily identified either using Doppler or by simple compression where the vein is easily compressed (Figs. S3A,B).

Once access is obtained a 6- to 10-French sheath is placed in the right femoral vein. It is recommended early in the implanter experience to perform a venogram of the femoral and iliac vein to screen for any stenosis or tortuosity that might hinder advancement of the Micra introducer (Fig. S4). The left femoral vein may be used for implantation in case the right femoral vein anatomy prohibits the introduction of the Micra system; this should be strongly considered in case of inadvertent femoral arterial puncture.

After obtaining the venogram, the next step is to guide a stiff guide wire (Amplatz Super Stiff guide wire, Boston Scientific or similar) up into the superior vena cava (SVC). The introducer will be placed over this wire. If any resistance is felt during advancement of the super stiff wire a venogram should be performed to understand the origin of the resistance. In this case, an exchange method in which a softer wire is guided through the tortuosity up to the SVC, followed by advancing a long sheath and then exchanging the soft wire for the super stiff wire should be considered.

Dilation of the entry site is then performed using sequentially increasing diameter dilators (12-French and 18-French) in anticipation of placement of the Micra introducer system (23-French inner and 27-French outer diameter).

The Micra introducer system is flushed with 30–50 mL of saline, wetting the surface to activate the hydrophilic coating, allowing the introducer to slide more easily. Under fluoroscopic guidance the introducer system is advanced through the femoral vein and into the RA (Supplementary video 1). While advancing the system, one might need to continuously rotate the introducer clockwise (CW) and counter-clockwise (CCW) to facilitate its movement in the venous circulation. The introduction of the 23-French introducer may be painful and in some instances lead to marked vasovagal reaction. Adequate local anesthetics and additional level of sedation with opiates and benzodiazepines may be needed in these cases. Atropine may be given preemptively to avoid the vasovagal response in otherwise bradycardic patients. The radiopaque marker band on the tip of the introducer should be positioned in the mid-RA; hence, the dilator must be advanced to the SVC while always leading with the guide wire and following with fluoroscopic guidance (Fig. 2). The dilator and wire are then withdrawn and a large 60 cc syringe is used to aspirate 35 cc of blood and re-flush the introducer with warm saline (35 °C/95 °F). The side port of the introducer is then attached to a heparin drip with a constant flow rate (approximately 2–5mL/min or 100–300 mL/h) to prevent clot formation within the Micra introducer. In addition, consider a low-dose bolus of heparin (2,000 to 5,000 units) delivered intravenously following placement of the introducer to assist in the prevention of clot formation on the device and delivery tool. The procedure can be safely performed on vitamin K antagonists with an INR<3.0.

Guiding the Delivery System to the RV

The Micra delivery system is then prepared by flushing, first with the device outside the device cup (how it is packaged) and then again after pulling the device back into the device cup (ready for implant). Continue flushing slowly while inserting the delivery tool into the introducer. The Micra delivery system is advanced through the introducer until the black outer sheath on the delivery tool reaches the hemostasis valve on the introducer. Advancing the delivery tool under fluoroscopy past this position leads to alignment of the radiopaque marker band on the end of the device cup and the marker band on the end of the introducer (Fig. 3).

The introducer system is pulled back into the inferior vena cava (IVC) approximately 2 device lengths while the delivery system remains in the RA fixed in its position (Fig. 4). It is crucial not to advance the delivery system out of the introducer in order to avoid inadvertent RA perforation.

The delivery system is curved using the deflection button on its handle in order to cross the tricuspid valve (TV) into the RV (Supplementary video 2); CCW rotation of the system might be needed to direct the system anteriorly toward the TV. A combination of fluoroscopy in RAO and LAO views allows safe passage across the tricuspid valve with little forward pressure, thus reducing the risk of RA perforation. A continuous small deflection of the cup helps to avoid adding pressure to the cup when it is trapped against the tricuspid valve or trabeculae. It is recommended to avoid having the cup “pop” through the valve as this could cause injury or perforation to the RV. In the majority of cases crossing the valve is relatively easy; however, at times it might take additional maneuvering as the delivery system might get caught on the valve or the inter atrial septum. Once across the TV, the deflection should be released to avoid directing the tool toward the inferior free wall. A slight CW torque should be applied to direct the system to the mid to low septum. The position of the system should be verified in the RAO and
Figure 3. AP view of Micra Delivery system inside the Introducer positioned in the RA. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology’s website: www.wileyonlinelibrary.com/journal/jce

Figure 4. AP view of Micra delivery system in RA as introducer system is withdrawn.

LAO orientation (Supplementary videos 3,4). Prior to any tip pressure being placed on the delivery system, contrast injection (50:50 contrast:saline) is recommended to verify position of the Micra pacemaker and ensure the free wall has been avoided (Fig. 5). Dilution of the contrast reduces the risk of “pushing” the Micra out of the cup with the contrast injection.

Deploying the Device

Deploying the Micra pacemaker requires a slow and very controlled motion that ends with the delivery system in the RV (Supplementary video 5) but around 2 device lengths away from the Micra pacemaker (Fig. 6).

This step-by-step approach begins with unlocking the tether and removing the tether pin once the desired implant location had been confirmed. A fine forward pressure on the delivery system is applied by slowly advancing the delivery system until a concave curve is seen at the bend of the system just proximal to the device cup (Figs. 5 and S5).

It is important to have adequate tip pressure to ensure stable attachment of the tines and good electrical measurements. Ensuring a more septal position of the device allows for the safe application of pressure at this stage of the procedure. A fine balance exists between too much and too little pressure; if not enough pressure is applied fixation
is likely to be inadequate and electrical values are likely to be poor. With experience, this fine balance is easily recognized and the operator will acquire a better feel for how much pressure to apply. Once adequate tip pressure is achieved, the device is deployed about half way observing the tines exiting the device cup and engaging the tissue. Once the device is deployed half way the forward pressure on the delivery system is relieved by gentle withdrawal of the delivery system from the introducer, which prevents any forward or superior movement of the cup on the device as the Micra is fully exposed. It is not uncommon to observe premature ventricular contractions during this part of the procedure.

Testing the Device

Once deployed, either the fixation test (pull and hold) or the electrical testing can be performed. While electrical testing can be performed before the fixation testing, it is imperative that the electrical testing be repeated after the fixation testing. If electrical measurements are acceptable (≤ 1.0 V @ 0.24 m, R waves ≥ 5 mV, impedance 400–1,500 ohms) the pull and hold test should be performed. The pull and hold test is performed by pulling on the tether until the heart beat is felt and then cine at 15 frames in a magnified frame for 2–3 seconds. The cine is then reviewed frame looking for tines that open 10–30 degrees or more by frame (Supplementary video 6). If less than 2 tines are observed to open then the pull and hold test can be repeated with more tension and/or in another fluoroscopic angle. Consider both LAO and RAO angulation as well as cranial caudal angulation, as the Micra can be in many orientations. Movement of 2 out of the 4 tines is all that is required to determine adequate fixation (Fig. 7) otherwise the Micra should be repositioned.

Once fixation is confirmed the electrical parameters should be measured. In case of elevated pacing capture thresholds, it is prudent to wait 5–10 minutes and retest before recapturing and redeploying the Micra, as often capture thresholds improve with time. If suboptimal electrical values are being considered, the expected device longevity chart should be consulted to understand the impact of longevity on the specific patient. Recapture and reposition of the Micra device is needed in case the electrical measurements or stability are inadequate.

Recapture and Reposition

While the first position is adequate in most of the Micra implantations (Fig. S6), recapturing the device is relatively straightforward and gives the operator freedom to position the device multiple times with little risk to the patient.

The process of recapturing the Micra pacemaker should be done by using the tether as a rail and pulling low and constant tension on the tether rather than simply advancing the delivery system; this should allow the Micra device and the recapture cone to align. Once the recapture cone and the device are coaxial, the tether should be locked and the delivery cup should be advanced over the device by pushing the blue deployment knob toward the distal end of the handle (Supplementary video 7). Care is required at this stage to ensure that no myocardial structures are caught within the cup of the delivery tool. Occasionally there is difficulty either advancing the delivery system back to the device or retracting the device back into the device cup. This may be caused by capturing parts of the valve apparatus or myocardial trabeculae. If any resistance is felt on the deployment knob during recapture, a repeated recapture attempt is required with different axis of the delivery tool to clear the system path to get back to the device.

Once the Micra is successfully recaptured it is maneuvered into a different location and the deployment process is repeated. One should avoid manipulating the deflection of the delivery system while trying to recapture the device to avoid damage to the delivery system.

Removing the Tether

Once the Micra is deployed with adequate fixation and electrical parameters, the tether must be removed to release the Micra. To minimize any friction of the tether in the delivery system or device caused by blood clots, the delivery system should be flushed intermittently or continuously during the entire procedure with heparinized saline. The first step in tether removal is bringing the delivery tool recapture cone close to the Micra device mimicking the procedure to recapturing the Micra. This is done to create support in case tension develops during tether removal. The 2 sides of the tether are pulled back and forth (“flossed”) while watching on fluoroscopy to ensure they move freely through the system as preparation for cutting the tether. If high tension is felt, the delivery tool can be advanced or retracted a cm or two to change the interaction of the tether with the heart. Once the tether is loose, the tether with the higher tension is then cut. The tether is retracted slowly while monitoring the Micra pacemaker position on fluoroscopy. The retraction of the tether should be done with less force than the pull and hold test to avoid device dislodgement. In some cases it may take several minutes of low constant tension for the tether to move freely and the device to be released. It may come out slowly with a few centimeters released with each heartbeat, and patience is needed in this situation. Once the tether is fully removed, the delivery system can then be removed from the introducer leaving the Micra in the final position (Fig. S7) (Supplementary video 8).
A repeated fluoroscopic check as well as a last electrical measurement is suggested at this point, as this is the moment when device recapture may be performed if needed, as all the tools are still available.

**Removing the Introductor and Obtaining Hemostasis**

Upon removal of the sheath the skin can be closed in a number of different ways:

- Application of pressure
- Figure of eight stitch
- Single or double purse string

**Discussion**

In this report we summarized the different steps for safe implantation of a tine-based leadless pacemaker from venous access to hemostasis. The critical steps include careful patient selection, careful navigation around the RV to avoid perforation, and careful removal of the tether at the end. The specific steps described were:

1. Venous access and positioning the introductor
2. Guiding the delivery system to the RV
3. Deploying the device
4. Testing the device
   a) Pull and hold test
   b) Electricals
5. Recapture and reposition (if required)
6. Removing the tether
7. Removing the introductor and obtaining hemostasis

Collectively, these steps can be done in 30–40 minutes at first and then closer to 20 minutes after 5–10 implantations (5).

In the Micra global clinical trial, the Micra system was implanted with high success (99.2%) in more than 700 patients by 94 operators worldwide with an excellent safety and performance profile. The overall major complication rate for Micra was 51% lower than the historical control of leadless pacing in a patient with a bioprosthetic tricuspid valve. J Interv Card Electrophysiol 2015;44:89-90.

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**Supporting Information**

Additional supporting information may be found in the online version of this article at the publisher’s website:
**Figure S1.** Access centrally to the femoral vein may reduce the risk of femoral venous laceration.

**Figure S2.** Ultrasound (with Doppler) illustration of femoral vein deep to artery. Following the course of the artery/vein caudally or cranially will usually identify a location where the 2 separate to allow safe cannulation.

**Figure S3.** Compression of vessels clearly delineates artery and vein.

**Figure S4.** Femoral and iliac veins venogram showing the smaller caliber vein early in its course.

**Figure S5.** “Gooseneck” appearance of the Micra delivery system prior to deployment.

**Figure S6.** Micra TPS deployments during implant. (Duray GZ et al. “Looking beyond 6 months: Results from the Micra Transcatheter Pacing Study.” Presented at Cardiostim-EHRA Europace, Nice, France. June 9, 2016.).

**Figure S7.** Micra device in final position.

**Video S1.** Advancing the introducer up the femoral vein.

**Video S2.** Crossing the tricuspid valve.

**Video S3.** Navigating in the right ventricle.

**Video S4.** LAO view of Micra delivery system directed to the septum.

**Video S5.** Delivering the Micra device.

**Video S6.** Pull and hold test.

**Video S7.** Device recapture.

**Video S8.** Releasing the device.