

# Potential compression neuropathy of the femoral nerve caused by the delivery sheath of a transcatheter leadless pacemaker



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## Introduction

Currently, 2 manufacturers have introduced leadless pacemaker systems: the Micra Transcatheter Pacing System (Medtronic, Minneapolis, MN) and the Nanostim (Abbott, St. Paul, MN). Although their effectiveness and usefulness during short-term follow-up in humans were recently reported in a few studies,<sup>1–4</sup> lethal complications such as cardiac perforation and tamponade, deep venous thrombosis, and retroperitoneal hemorrhage occurred during the implantation procedures, and their safety over a longer follow-up period remains to be fully clarified. From the anatomical point of view, femoral nerve injuries related to the large-bore delivery system used during femoral venous access may be a potential complication. We present a patient who transiently suffered from intense tearing pain of the right thigh probably owing to compression of the L2 and L3 nerves by the large-bore delivery sheath used.

## Case report

An 86-year-old Asian woman (height: 147 cm, weight: 48 kg) with a medical history of primary polycythemia and spondylolisthesis was referred to our hospital because of several episodes of syncope. An auto-trigger loop recorder showed bradycardia-tachycardia syndrome with sinus pauses of 5 seconds.

The implantation of a leadless pacing system (Micra Transcatheter Pacing System, Medtronic) was scheduled after obtaining the patient's informed consent. Under conscious sedation, right femoral venous access was obtained under ultrasound guidance. Once an 8F sheath (11 cm in length) was inserted, we performed femoral and

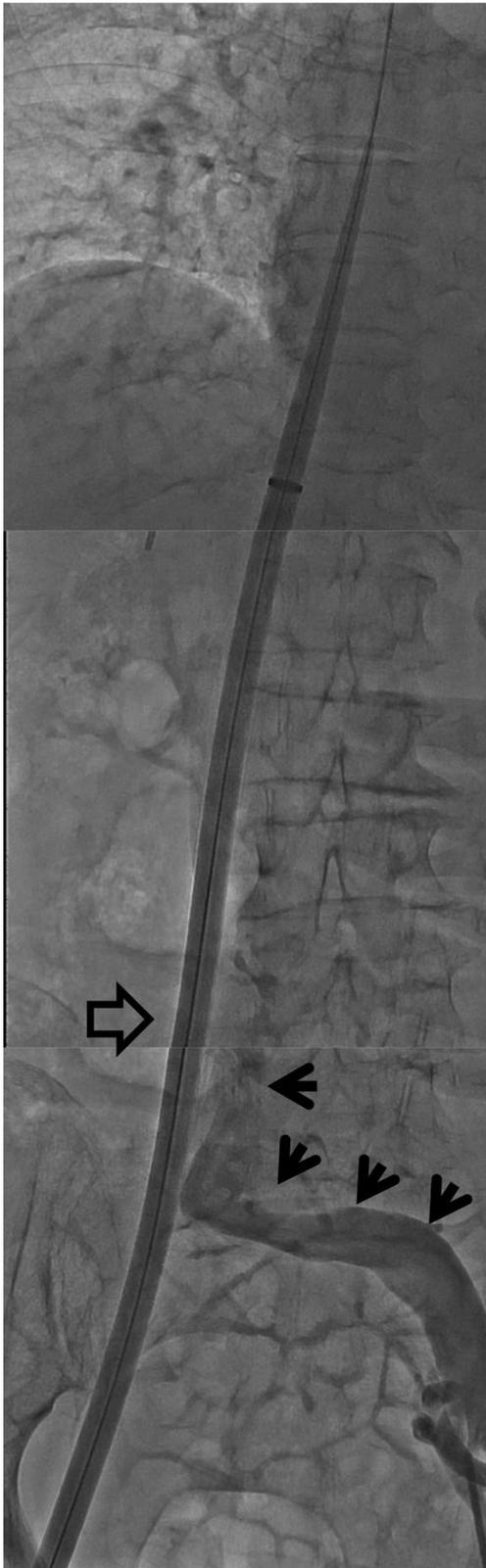
## KEY TEACHING POINTS

- Effectiveness, usefulness, and safety of the leadless pacemaker during short-term follow-up has recently been reported, but lethal complications such as cardiac perforation can occur during implantation.
- Compression neuropathy of the femoral nerve is a possible complication during implantation because the long, large, and stiff sheath could cause excessive extension and straightening of a strongly curved femoral vein, resulting in compression and stretching of the femoral nerve.
- If a patient complains of tearing thigh pain, the physician should either quickly perform the implantation to minimize the risk of permanent neuropathy or withdraw the introducer sheath, ascertain whether the symptom is resolved, and change the strategy to one of conventional transvenous pacemaker implantation.

iliac venography that revealed no stenoses or tortuosity. Next, we guided a super-stiff guide wire (Amplatz Super Stiff, Boston Scientific, Boston, MA) up into the superior vena cava, with no resistance felt during advancement. After dilation of the entry site using a short 16F sheath, the Micra 23F inner dilator was introduced, and we finally advanced the Micra 27F introducer sheath (Micra sheath) carefully and gradually (Figure 1). Although the insertion of the Micra sheath was performed without resistance or complaints of pain from the patient, when the Micra sheath had advanced to near the kidney (Figure 1), the patient began to suffer from intense tearing pain of the front and lateral aspects of the right thigh. The surface pain region of the right thigh was clearly confined to the dermatomal distribution of the L2 and L3 femoral nerves (Figure 2). The pain was not

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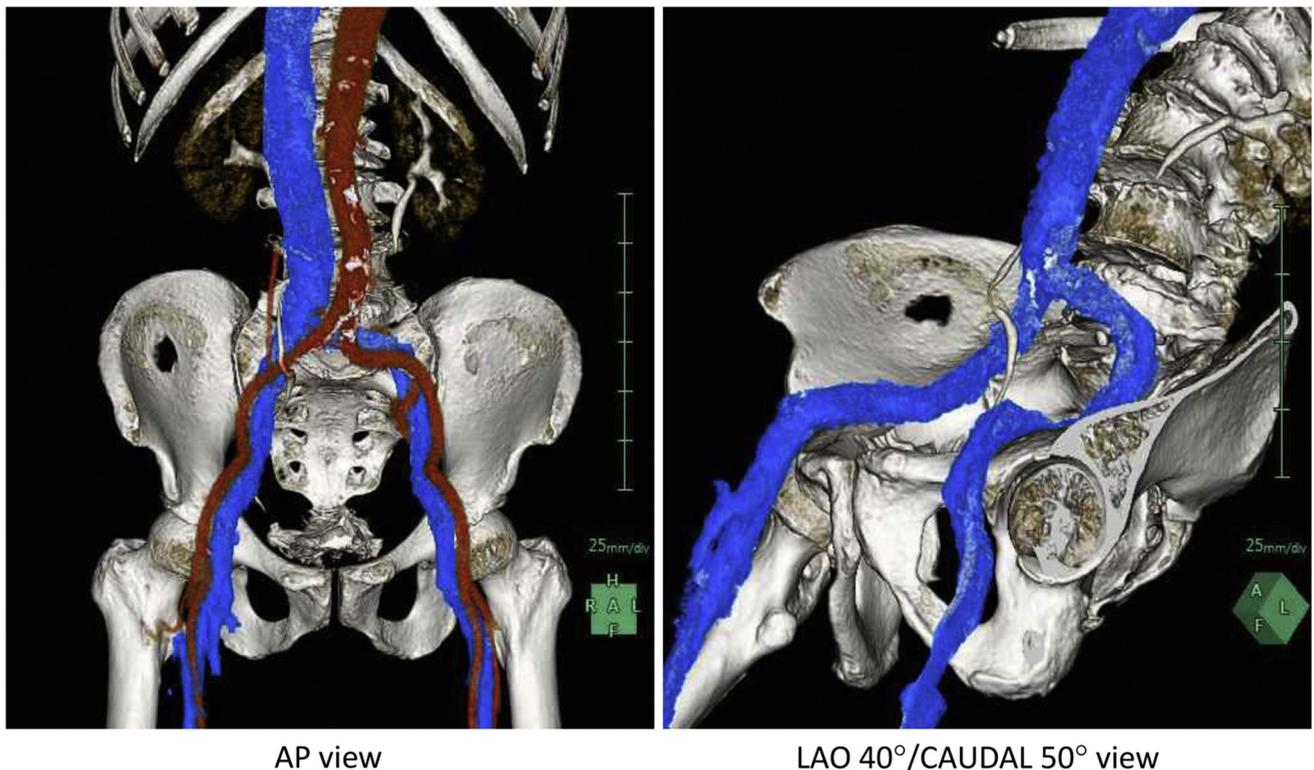
**Figure 1** The Micra sheath (Medtronic, Minneapolis, MN) and femoral venography. The contrast was injected from the left femoral vein (*closed arrows*). This fluoroscopic view suggests that the Micra sheath (*open arrow*) forcibly straightened the right femoral vein.



**Figure 2** The region of pain, as shown by the black line, is distributed along the sensory area of L2 and L3. The puncture site was outside the region of pain and did not appear to be swollen.

relieved by any analgesics (lidocaine, pentazocine, and hydroxyzine hydrochloride).

Neither the puncture site nor the region of pain seemed to be swollen (**Figure 2**). No other sensory or motor abnormalities were present in the right leg, and the leg distal to the access site was neither cold nor pale. We decided to halt the implantation procedure and convert to the transvenous implantation of a conventional pacemaker. Of note, the tearing pain disappeared immediately after the Micra sheath was withdrawn. After the implantation of a standard transvenous single-chamber pacemaker, a computed tomography (CT) scan showed no evidence of arterial or venous perforation, bleeding, any hematoma at the vascular access site, or



**Figure 3** Anatomy of the bilateral femoral veins as depicted by 3-dimensional computed tomography. The left anterior oblique (LAO)/CAUDAL view clearly shows the strongly curved femoral veins. The long-axis diameter of the right common femoral vein was 10.7 mm. AP = anteroposterior.

retroperitoneal hemorrhage. A 3-dimensional (3D) reconstruction of the CT image showed the right femoral vein and inferior vena cava to be strongly curved (Figure 3). Magnetic resonance imaging showed lumbar spondylolisthesis but no tumors, growths, or any other masses in the area of the femoral nerve that could cause compression of the nerve. The patient was discharged without pain or neurologic deficit. We believe that compression and extension of the femoral nerve by the Micra sheath was the probable reason for the transient pain distributed along the sensory area of the L2 and L3 femoral nerves.

## Discussion

Leadless pacemaker implantation using a large-bore long sheath is a complex procedure requiring adequate experience and technical skill of the operators. Currently recognized major complications have been fatal. Although femoral nerve injury is considered a nonfatal complication and would resolve over time, it could be a dominant and irreversible complication, the consequences of which could significantly affect a patient's quality of life. Femoral nerve injuries are more common during femoral artery access than during femoral vein access. The incidence of femoral nerve injury caused by femoral artery access during cardiac catheterization procedures was 0.2% in a single-center study of 9585 procedures between 1988 and 1993<sup>5</sup> and 0.000038% in the data file from the

National Inpatient Sample study of 15,894,201 procedures between 2002 and 2010.<sup>6</sup>

El-Chami and colleagues<sup>7</sup> provided advice on the venous access method when implanting a leadless pacemaker. Because the introduction of the Micra sheath may be painful and lead to marked vasovagal reaction, adequate local anesthetic and an additional level of sedation with opiates and benzodiazepines is needed. Although general anesthesia or deep sedation may relieve patient discomfort, physicians can lose the ability to recognize signs of femoral nerve injury, and prolonged compression and extension of the nerve could cause irreversible damage of the femoral nerves, leading to disabling motor neuropathies.

The Micra sheath comes in only 1 size: 27F (9.0 mm). Our patient was an 86-year-old woman with a small body size (height: 147 cm, weight: 48 kg, body mass index 22.1). Her common femoral vein diameter was 10.7 mm. A previous case report described a small female patient with a low body mass index of 16 kg/m<sup>2</sup> (height: 145 cm, weight: 33 kg) who underwent implantation of a Micra without complications.<sup>8</sup> Although her femoral vein size was 8.53 mm in diameter, the distensible nature of the venous system may accommodate up to a 27F sheath. Also, there was a case report describing a 12-year-old 37-kg girl with a history of repaired tetralogy of Fallot who successfully underwent implantation of a leadless pacemaker (Micra).<sup>9</sup> Because invasive procedures are

commonly performed under general anesthesia in pediatric patients, complications may more likely be underrecognized than those in adult patients.

Not only a large bore size but also stiffness is required for the Micra sheath to support the Micra delivery catheter system in delivering the Micra to the appropriate position in the right ventricle, although the shaft of the delivery catheter is flexible and mobile. A large and stiff sheath could cause excessive extension and straightening of the curved femoral vein, resulting in compression and stretching of the femoral nerve. Preoperative imaging such as venography and ultrasonography can allow accurate measurement of the diameter of the femoral vein. However, these modalities cannot estimate the 3D venous flexion of the vein. 3D CT can be useful in assessing whether the anatomy and femoral vein size are adequate to accommodate a large-bore stiff sheath.

## Conclusion

Compression neuropathy of the femoral vein is a possible complication during the implantation of a leadless pacemaker system. Physicians should be aware of this neuropathy, especially in small patients with strongly curved femoral veins. If a patient complains of tearing thigh pain, the physician should consider the possibility of compression neuropathy

and either quickly perform the implantation to minimize the risk of permanent neuropathy or withdraw the introducer sheath, ascertain whether the symptom is resolved, and change the strategy to one of conventional transvenous pacemaker implantation.

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