

SPOTLIGHT

Perforation of the right atrial appendage during implantation of a leadless pacemaker

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Leadless intracardiac pacemakers were developed to avoid the complications of the traditional transvenous pacing systems. The Micra™ transcatheter pacing system (Medtronic, Inc.), which is implanted in the right ventricle, was approved in 2016 by the Food and Drug Administration (FDA). A pivotal clinical trial reported a high rate of implant success and a safety profile similar to that of transvenous pacemakers.¹ In September 2017, Micra™ was made available for reimbursement under insurance in Japan, and the number of implantation cases has been increasing since. The incidence of cardiac perforation was approximately 1.5% in investigational trials; however, the major complication rate in studies in the postapproval registry of Micra™ was lower than that in the investigational study.² Nevertheless, cardiac perforation remains a major complication.

A 94-year-old woman was urgently admitted to our hospital because of exacerbation of heart failure. She had a history of myocardial infarction and was receiving oral treatment for chronic renal and chronic heart failure; however, she did not have a history of chronic obstructive pulmonary disease. She was 141 cm tall, weighed 40 kg, and had a body mass index (BMI) of 20.4 kg/m². Echocardiography showed good left ventricular contractility, however, electrocardiography at admission showed complete atrioventricular block without atrial fibrillation, which was deemed the cause of exacerbated heart failure. The need for a pacemaker was indicated by cardiologists, for which Micra™ implantation was selected considering their experience with Micra™ in more than 20 cases. The right femoral vein approach was used for the procedure under local anesthesia. The patient experienced chest pain and decreased blood pressure during Micra™ delivery system deployment, and pericardial effusion was noted, suggesting cardiac perforation. Venous arterial extracorporeal

membrane oxygenation (VA-ECMO) from the left femoral artery and vein was immediately established and the hemodynamics became stable. Consent was subsequently obtained from the patient and her family. She was then transferred to the operating room and general anesthesia was induced. Emergency median sternotomy was performed, and surgical findings are shown in Figure 1. The atrium was filled with dark, bloody pericardial fluid, and the Micra™ delivery sheath had pierced the right atrial appendage and protruded from the heart, with venous bleeding from the perforation. The delivery sheath was slowly pulled out of the femoral vein and removed, and the perforation was sutured closed. Since the hemodynamics were stable, VA-ECMO was withdrawn during the surgery, the epicardial leads were sewn into the atrium and ventricle, and the chest was closed. We guided the epicardial leads subcutaneously below the left clavicle for future placement of the pacemaker generator. The total operation time was 189 min and intraoperative blood transfusion was required. She was transferred to the intensive care unit under ventilation management, extubated 16-h later, and underwent dialysis temporarily for oliguria for 2 days. A generator was placed 15 days postoperatively by a cardiologist. The patient required time to rehabilitate, considering her old age; however, she was finally discharged on the 59th day of illness. Figure 2 shows chest X-ray images immediately before surgery and before discharge. No particular impairment of cardiac function was observed postoperatively.

Regarding the clinical results of Micra™, implantation safety was evaluated in 19 countries including Japan. A total of 725 patients were newly implanted, with successful implantation performed in 719 patients. At the 6th-month follow-up, the rate of major complications such as death, hospitalization, and system replacement was 4%, which is lower than the 7.5% with intravenous pacemakers.²

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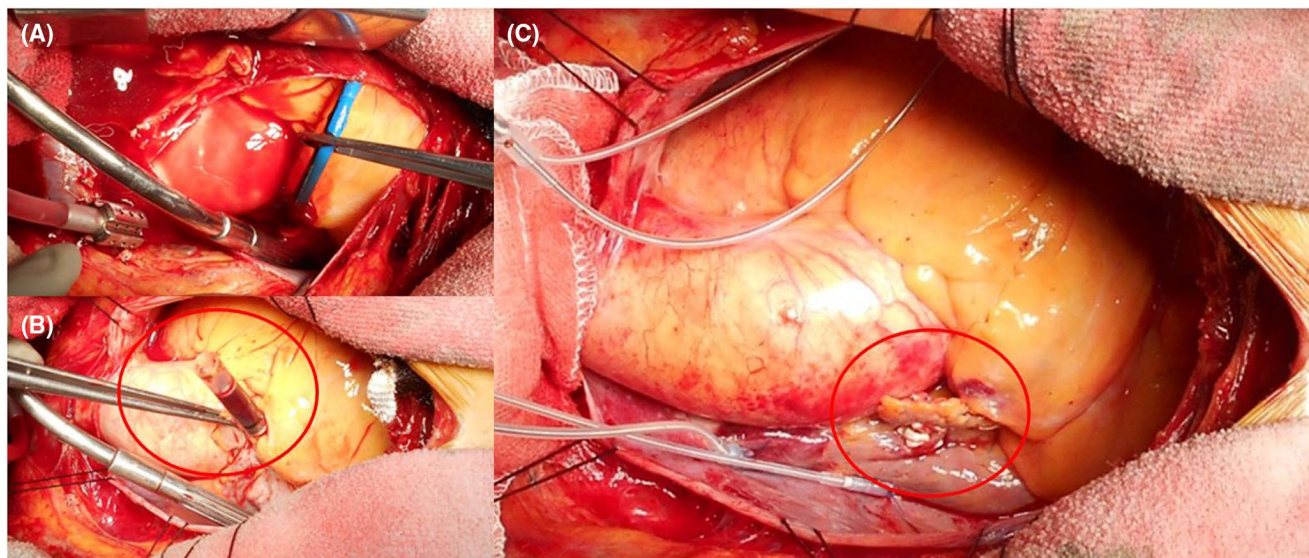


FIGURE 1 Intraoperative photos: left, caudal side and right, cranial side. (A) Accumulation of a dark bloody pericardial fluid is observed in the pericardial sac. (B) Perforation from the right atrial appendage to the extracardiac site. (C) Suturing and closing of the perforation and sewing of the epicardial leads

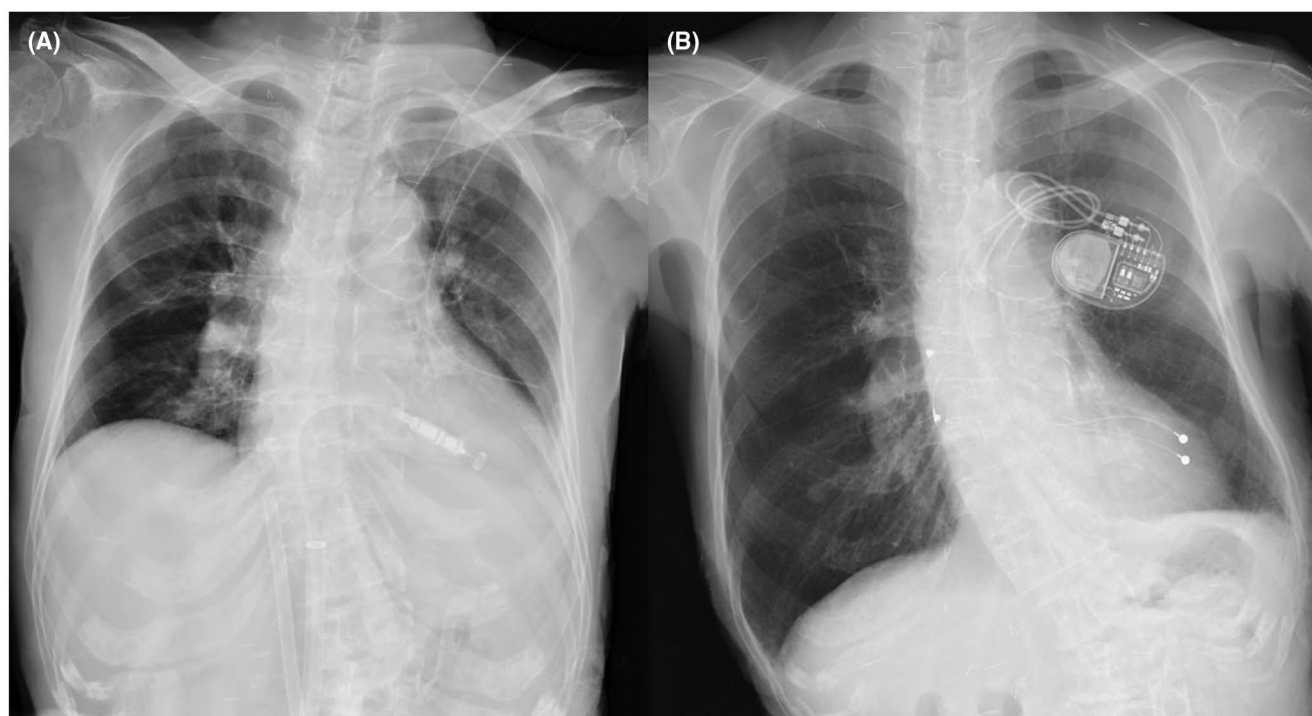


FIGURE 2 Chest X-ray images. (A) Venous arterial extracorporeal membrane oxygenation establishment before surgery and (B) before discharge

Amine et al. reported the implantation results of Micra™ in 129 patients, of whom 44 (34.1%) were aged ≥ 90 years, and the rate of implantation success was 97.6%, with no major complications. During a mean follow-up of 230 ± 233 days, 13 (31.7%) patients died; however, no device-related deaths were observed. Therefore, they concluded that Micra™ is effective and is relatively safe for patients aged ≥ 90 years.³

Hauser et al. analyzed the FDA's Manufacturer and User Facility Device Experience database for Micra™ implantation and reported on complications. An analysis of 363 patients with major complications reported between 2016 and 2020 revealed that 287 (79.1%) developed cardiac tamponade and 96 (26.4%) died, which were 3.4 and 10 times higher than the complications reported for conventional intravenous pacemaker implantation, respectively. Further

analysis of the 96 patients who died revealed that cardiac perforation associated with the Micra™ implantation was characterized by fatal bleeding and rapid deterioration of circulation because of cardiac tamponade. The most common perforation site was the free wall of the right ventricle; however, right atrial perforation was also observed in two cases.¹

The risk factors for pericardial effusion and tamponade development with leadless pacemaker implantation include a BMI of <25 kg/m², age of >85 years, female gender, chronic lung disease, congestive heart failure, and nonatrial fibrillation. The total number of risk factors was correlated with myocardial injury, rising from 1% for two total risk factors to 2.9% for three.^{2,4} This case had five risk factors, making it a high-risk case. Micra™ may be indicated for patients with nonatrial fibrillation when atrial lead placement is difficult, high-risk, or ineffective; however, it is not clear whether this is true in the present case.

To the best of our knowledge, there have been no reports of perforation of the right atrial appendage during placement of a leadless pacemaker in Japan. To avoid complications such as the one in this case, we should carefully consider the risk factors for the indication of Micra™.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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