Cautionary tale of right ventricular perforation during Micra™ leadless pacemaker insertion

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Abstract
Transcatheter pacing systems are self-contained, leadless, devices that offer the potential benefits of avoiding complications related to pectoral pocket and upper extremity vascular access. These systems in preapproval trials demonstrated excellent safety profile with the incidence of device-related cardiac perforation as low as 1.6% with Micra™ (Medtronic) and 1.3% in Nanostim (Abbott). In post-approval registry of Micra™ TPS, the rate of major complications was even lower than in the investigational study ranging from 0.63% to 0.77%. Recently, published report found much higher rates of need for rescue surgery, shock, tamponade, and death among patients implanted with the Micra™ device when compared with transvenous devices. This case report describes two cases of major right ventricular perforation requiring surgical intervention.

KEYWORDS
cardiac perforation, cardiac tamponade, leadless pacemaker, Micra, right ventricular perforation

1 | INTRODUCTION
Transcatheter pacing systems (TPS) are self-contained, leadless, devices comprised of a generator, electrode(s), and an active fixation mechanism. These systems offer the potential benefits of avoiding complications related to pectoral pocket and upper extremity vascular access. In preapproval trials, the incidence of device-related cardiac perforation was 1.6% with Micra™ (Medtronic) and 1.3% in Nanostim (Abbott). The Micra device received FDA approval in 2016. In post-approval registry of Micra™ TPS, the rate of major complications was lower than in investigational study ranging from 0.63% to 0.77%. Comparatively, a recently published report found higher rates of need for rescue surgery, shock, tamponade, and death among patients implanted with the Micra™ device when compared with transvenous devices. This manuscript describes two cases of major right ventricular perforation requiring surgical intervention.

1.1 | Case 1
An 80-year-old woman with history of hypertension, inflammatory bowel disease, hyperlipidemia, atrial fibrillation, chronic kidney insufficiency, psoriasis, and breast cancer was hospitalized for syncopal episodes secondary to atrial fibrillation with tachy-brady syndrome. The patient was scheduled for placement of a Micra™ TPS and ablation of the atrioventricular (AV) node. The procedure was performed while the patient was anticoagulated with a therapeutic dose of heparin. After...
femoral venous access was obtained, a delivery catheter was advanced across the tricuspid annulus and directed toward the RV septum. Left anterior oblique (LAO) view was obtained to ensure the delivery system placement against the septum. Contrast was injected through the delivery system to confirm septal position. The device was advanced from the delivery system. Myocardial perforation was suspected when the patient became hypotensive, and a new pericardial effusion was noted. Micra™ device was retrieved. A percutaneous pericardial drain was inserted, and dark blood was aspirated. Patient experienced electromechanical dissociation cardiac arrest and cardiopulmonary resuscitation (CPR) was initiated. Spontaneous circulation was restored, yet patient remained hypotensive. Due to the patient’s continued instability, the decision was made to proceed with median sternotomy in the electrophysiology suite. Once the pericardium was opened, 2 L of dark blood was evacuated. A large, linear 2 cm laceration in anterior wall of RV, next to the septum, was identified. The tear in RV was repaired with several pledged horizontal mattress sutures. The patient’s postoperative course was uneventful. On postoperative day (POD) 7, she underwent an ablation of her AV node followed by placement of a transvenous single chamber pacemaker. Patient was discharged to a rehabilitation center on POD 9.

1.2 | Case 2

An 83-year-old woman with a history of hypertension, non-insulin-dependent diabetes mellitus, and stroke presented with intermittent dizziness. Electrocardiographic evaluation revealed high-grade AV block in the setting of beta blocker and clonidine use. She was observed for 5 days while AV node blocking agents were held, but there was no improvement in AV conduction. A leadless pacemaker was recommended.

During the procedure, the delivery catheter was directed towards the mid-RV septum, as confirmed by LAO view on fluoroscopy. After contrast injection to confirm septal position, a small amount of contrast was noted to be extravasating into the pericardial space. Of note, the Micra™ pacemaker tines were not deployed at this time. The patient was hemodynamically stable at this point. The delivery catheter was then repositioned to lower RV septal location, with confirmation using contrast injection. During deployment of Micra™ tines at this site, the patient became hemodynamically unstable and large contrast extravasation into the pericardial space was noted. The patient developed cardiac tamponade and a pericardial drain was inserted percutaneously. Despite the removal of 1.5 L of blood with autotransfusion, the patient remained unstable with persistence of large pericardial effusion by echocardiogram. Due to the continued instability, subxiphoid pericardial window revealed hemopericardium, with ongoing bleeding; therefore, a sternotomy was performed. A large circular opening in the RV was identified adjacent to the septum in free RV wall. Initial attempts to close the tear were unsuccessful. Suture re-approximation of tear demonstrated friable tissue with some initial tearing of the myocardium. The decision was made to initiate cardiopulmonary bypass to facilitate decompression of the heart with hemodynamic stability. The defect was repaired with four pledged horizontal mattress proline sutures placed along the length of the defect.

2 | DISCUSSION

Cardiac perforation during insertion of a TPS system is a rare, but recognized complication. Some have postulated that myocardial perforation with TPS carries more profound morbidity and higher mortality than perforation secondary to conventional transvenous lead implantation. Questions fundamental to understanding this apparent discrepancy are: (1) is there an increased rate of perforation in TPS systems? and (2) are perforations with the TPS system inherently more likely to require surgical intervention? Mechanism of perforation may influence the severity of the perforation. Currently available conventional transvenous pacing (TVP) leads are 6–7 French in size and are flexible in nature and can perforate the RV at their tip. The flexible anchoring tines of the leadless ppm are only 1 mm wide and may perforate the RV during deployment. Additionally, it may be possible that these small tines on the device may cause a traction injury if the device remains attached to the delivery system after deployment for prolonged period of time while pushing against thin contracting-free RV wall. The delivery catheter for the currently FDA-approved TPS utilizes a 23-French delivery sheath and is rigid. Although perforation by a transvenous lead or TPS anchoring tines may result in a relatively small perforation, a perforation with the rigid 23 French TPS delivery sheath would be expected to create a potentially much larger defect.

2.1 | Rate of effusion

Pre- and post-market reports described acceptable safety profile of the device with cardiac perforation rate of 1.6% in pre-approval study of Micra™ system, and much lower rate of cardiac perforation in post-approval registry of Micra™ TPS of 0.63%–0.77%. Not all perforations meet the criteria for major complications, as many small effusions do not require an intervention. In the preapproval study, the rate of cardiac perforation requiring intervention was 1.38%. In initial post-approval studies, the rate of perforation requiring intervention was only 0.13% and 0.44% in subsequent study. This rate of perforation is comparable to cardiac perforation due to conventional transvenous lead systems, which is reported as 0.8% in a meta-analysis of 28 studies including over 60,000 patients.

2.2 | Rate of surgical intervention

The recent report by Hauser et al utilized the Food and Drug Administration’s (FDA) Manufacturers and User Facility Device Experience (MAUDE) database to compare the incidence of major adverse clinical events between Micra™ system and an active fixation
TVP leads (CapSureFix™, Medtronic). Micra™ system had an expected number of procedural death and surgical complications compared to conventional TVP lead placement: Micra™ system had 11.0 times more death and 3.4 times more cases of acute cardiac tamponade. Additionally, more Micra™ patients required rescue surgery to repair myocardial and vascular perforations and tears than CapSureFix™ implants. Finally, more Micra™ patients required CPR than CapSureFix™ recipients.

In two cases described in our report, the defects in the RV were relatively large and therefore could not be managed conservatively. In fact, data from MAUDE database describe larger size cardiac perforations with TPS, hence a higher need for surgical intervention and repair. In both cases, the perforations were in anterior free wall of RV, which was consistent with the most commonly reported tear locations.\(^5\) Since the introduction of Micra™ system, the rate of serious procedural injuries resulting in death during implantation of this system in MAUDE database has trended up from 6.7% in 2016 when the device was FDA approved per 100 complications reported to 31.7% in 2020.\(^5\)

Nanostim leadless system which uses an 18 French delivery sheath, and an active fixation helix was evaluated in three clinical trials in a total of 1029 patients\(^2,8,9\) with a cumulative rate of cardiac perforation of 1.9% and mortality of 0.5%. This perforation rate is higher than the one reported for Micra™ device.

These data suggest surgical backup is reasonable to consider for leadless pacemaker systems insertions as cardiac perforation with the delivery system may result in a sizable defect. Clinical experience has demonstrated that prompt intervention on tamponade secondary to large perforations affords the best chance of survival.

**AUTHOR CONTRIBUTIONS**

All authors have contributed to data collection, interpretation, manuscript preparation, and review and have approved the final version of this manuscript.

**CONFLICT OF INTEREST**

The authors declare no conflict of interest.

**DATA AVAILABILITY STATEMENT**

The data that support the findings of this study are available on request from the corresponding author.

**ETHICS STATEMENT**

The study has been granted an exemption by the local ethics committee. Consents from both patients were obtained for the publication of this case report.

**TRANSPARENCY STATEMENT**

The lead author Iosif Gulkarov affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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