Percutaneous Simple Lead Traction Is a Feasible and Effective Method for Right Ventricular Lead Perforations

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Summary

Right ventricular (RV) lead perforations are relatively rare but a potentially life-threatening complication of surgical implantations of cardiac implantable electronic devices (CIEDs). The result of percutaneous simple lead traction after lead perforations in the Japanese population has not been well clarified.

We retrospectively studied 1359 patients (pacemakers [PMs], 973 patients; implantable cardioverter defibrillators [ICD], 386 patients) from April 2007 to December 2018 who underwent initial CIED implantation. Fifteen patients (1.1%) were diagnosed with RV lead perforations. The clinical data were evaluated in those patients, and the baseline characteristics and echocardiographic data were compared between the lead perforation group and the non-perforation group. The success and complication rates of the simple traction and repositioning of the RV lead were also assessed.

The number of perforated RV leads was seven ICD leads (1.8%) and eight PM leads (0.82%). They were diagnosed on a median seven days (5.5-36.0) after the CIED implantation. Twelve patients were asymptomatic but were detected by an increased capture threshold. Three patients had pericarditis and stimulation of the diaphragm. Only one patient in the ICD lead group who took anticoagulants had a cardiac tamponade and needed an urgent pericardiocentesis (0.07%). No one required a thoracotomy or other devices related to complications after repositioning the RV lead. There was no significant difference in the baseline characteristics and echocardiographic parameters between the groups.

RV lead perforations were relatively rare complications of CIED implantations. Percutaneous simple lead traction and repositioning the perforated lead was feasible and effective if the patients did not receive anticoagulants.

Key words: Pacemaker, Implantable cardioverter defibrillator, Lead perforation, Cardiac tamponade

Right ventricular (RV) lead perforations are relatively rare but a potentially life-threatening complication of implantations of cardiac implantable electronic devices (CIEDs). The incidence of RV lead perforations has been reportedly 0.1%-0.8% for pacemakers (PMs) and 0.6%-5.2% for implantable cardioverter defibrillators (ICDs).1-3 The clinical presentation was highly variable, ranging from asymptomatic to severe symptoms such as chest pain, dyspnea, and tamponades.4-6 Abnormal electrical parameters of PMs or ICDs may be the first clue to the diagnosis of cardiac perforations, but their diagnostic utility is limited by a poor specificity.7 Several methods for the management of this complication have been reported.4 However, the result of percutaneous simple lead traction after lead perforations in the Japanese population has not been well clarified. This study aimed to investigate the outcomes of percutaneous RV lead traction in patients who had lead perforations after the lead placement of a CIED.

Methods

Study subjects: We retrospectively studied 1414 patients from April 2007 to December 2018 who underwent initial CIED implantation. The exclusion criteria were the use of epicardial leads or pediatric cases (patient age of less than 18 years old). Fifty-five patients were excluded, and 1359 patients were enrolled in our study. A PM was implanted in 973 patients (DDD: 896, VVI: 54, VDD: 1, CRTP: 22) and an ICD or cardiac resynchronization therapy defibrillator (CRTD) in 386 (ICD: 259, CRTD: 127). We experienced 15 patients (1.1%, perforation group) with RV lead perforations. One patient (0.08%) who experienced right atrium (RA) lead perforation was excluded from this.
Figure 1. Chest computed tomography (CT) (A) and transthoracic echocardiogram (B) showing that the tip of the right ventricle (RV) lead was located outside of the heart (arrowhead), which suggested a perforation of the RV lead.

Figure 2. Uni indicates the unipolar electrogram from the tip of the RV lead. A dominant, upright R wave and inverted T waves were observed before withdrawing the lead, which suggested that the tip of RV lead was located in the epicardium. After withdrawing the lead, ST elevation was observed, which indicated that the tip of the lead moved to the endocardial side of the RV myocardium.

Diagnosis of RV lead perforations: RV lead perforations were suspected from the symptoms or an increased capture threshold (Bipolar). Ultrasound cardiography (UCG) or computed tomography (CT) was performed in such cases, and RV lead perforations were diagnosed by confirming that the tip of the RV lead was located outside of the heart (Figure 1). However, in cases with a minimal perforation of the heart, UCG or CT was non-diagnostic. Therefore, unipolar electrograms from the tip of the RV lead were confirmed before the lead traction. Lead perforations were also diagnosed by a dominant, upright R wave and an inverted T from the lead tip electrogram even in cases in which an imaging diagnosis was not performed (Figure 2).

Lead traction procedure: Antiplatelet therapy (aspirin, clopidogrel, prasugrel) and warfarin were not stopped, and direct oral anticoagulants (DOACs) (dabigatran, rivaroxaban, apixaban, edoxaban) were stopped on the day of the operation. Lead traction was performed under local anesthesia under sedation without intubation while a cardiac surgery team was on stand-by. The PM lead was removed from the RV myocardium by the simple traction method through subclavian vein access with invasive atrial blood pressure monitoring. After the lead was removed from the RV myocardium, we waited for more than 10 minutes to analysis. The clinical data in the perforation group was evaluated. Percutaneous simple lead traction and repositioning of the lead were performed in all patients. The baseline characteristics and echocardiographic data were compared between the lead perforation group and the non-perforation group. The success and complication rates of the strategy were also assessed.
confirm the absence of any complications. The same lead was repositioned to a different location.

**Statistical analyses:** The statistical analyses were performed using JMP® Pro, version 11.2 software (SAS Institute). The continuous variables were compared using the t-test. The categorical data were compared using the chi-square test. A value of $P < 0.05$ indicated statistical significance. This study was approved by the institutional review board of Saitama Medical University, International Medical Center (18-126).

### Results

**Baseline characteristics:** The baseline characteristics, echocardiographic data, and lead data were compared between the perforation group and the non-perforation group; however, there was no significant difference in any of the parameters (Table I). The perforation group consisted of 15 patients (1.1% of the total CIED implanted patients). The average age was 69.5 ± 9.3 years old, eight were males, eight had PMs, five had ICDs, and two had CRTDs (Table II). Four patients received a single antiplatelet therapy (SAPT), and two took a dual antiplatelet therapy. One patient took DOACs, and one took warfarin. One patient took SAPT and DOAC. Table III shows the number and details of perforated and non-perforated leads.

**Clinical features at the time of the presentation:** The median days from the implantation to the diagnosis was seven days (5.5-36.0) after the CIED implantation. One patient was diagnosed during the acute phase ($< 24$ hours), nine during the subacute phase (1 day to 1 month), and five during the chronic phase ($\geq 1$ month).\(^{11}\) Twelve patients were asymptomatic, but the lead perforations were detected by an increased capture threshold of the RV lead. Three other patients had pericarditis and stimulation of the diaphragm. No patients showed abnormal lead parameters for both RA and RV. No patients had any cardiac tamponades on the echocardiograms at the time of the diagnosis.

Thirteen patients underwent UCG, and in nine (69.2%), the tip of the RV lead was located outside of the heart. Nine patients underwent a CT scan, and a perforation finding was confirmed by CT imaging in all patients. A unipolar electrogram was recorded from the tip of the RV lead in all patients, and 11 patients (73.3%) had inverted T waves in the lead tip electrogram.

**Lead repositioning procedure:** The procedures were performed in the electrophysiology laboratory while continuously monitoring the atrial pressure. All leads were successfully extracted from the perforation site. Only one patient in the ICD lead group who took anticoagulants and SAPT had a cardiac tamponade and required an urgent pericardiocentesis (case 1). Although six patients took antiplatelet medications, and two took an anticoagulation therapy, they did not have any cardiac tamponades. No one required a thoracotomy or had any other device related complications after repositioning the RV lead.

Although one case showed that the perforated lead was located in the thoracic cavity, simple traction was successful without major complications (Figure 3).

### Discussion

**Main findings:** To the best of our knowledge, this was the first study to report the outcomes of percutaneous simple lead traction for RV lead perforations in the Japanese population. The main findings of this study were as follows: (1) RV lead perforations were relatively rare (1.1%), and cardiac tamponade was observed in one patient (0.07%) in this series of patients. (2) All perforated leads

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**Table I. Baseline Characteristics of Two Groups**

|                     | Perforation group ($n = 15$) | Non-perforation group ($n = 1344$) | $P$  |
|---------------------|-----------------------------|----------------------------------|------|
| **Background characteristics** |                             |                                  |      |
| Age                 | 69.4 (± 9.3)                | 70.9 (± 13.1)                    | 0.66 |
| Gender, Male, $n$ (%) | 8 (53.3)                    | 790 (58.8)                       | 0.67 |
| BMI, kg/m²           | 22.3 (± 3.2)                | 22.7 (± 3.8)                     | 0.70 |
| **Baseline heart disease** |                             |                                  |      |
| Ischemic cardiomyopathy, $n$ (%) | 4 (26.7)                   | 231 (17.2)                       |      |
| Non-ischemic cardiomyopathy, $n$ (%) | 3 (20.0)                   | 213 (15.8)                       |      |
| Valve diseases, $n$ (%) | 2 (13.3)                    | 150 (11.2)                       |      |
| Congenital heart disease, $n$ (%) | 0 (0)                      | 25 (1.9)                         |      |
| Idiopathic ventricular arrhythmia, $n$ (%) | 0 (0)                      | 30 (2.2)                         |      |
| The others, $n$ (%)   | 2 (13.3)                    | 70 (5.2)                         |      |
| **Echocardiographic data** |                             |                                  |      |
| LVEF (%)             | 57.6 (± 20.3)               | 57.5 (± 19.6)                    | 0.98 |
| LA diameter (mm)     | 41.1 (± 9.6)                | 40.4 (± 8.8)                     | 0.77 |
| LVDDd (mm)           | 48.7 (± 6.6)                | 49.6 (± 9.6)                     | 0.73 |
| IVST (mm)            | 11.2 (± 3.0)                | 11.2 (± 2.8)                     | 0.95 |
| PWT (mm)             | 10.2 (± 1.7)                | 10.6 (± 2.0)                     | 0.45 |
| **Lead data**        |                             |                                  |      |
| Pacemaker lead, $n$ (%) | 8 (53.3)                   | 960 (71.9)                       | 0.11 |
| Passive fixation lead, $n$ (%) | 0 (0)                      | 6 (0.45)                         | 0.71 |
| Lead position, RVA, $n$ (%) | 12 (80.0)                  | 1046 (77.8)                      | 0.84 |

BMI indicates body mass index; LVEF, left ventricular ejection fraction; LA, left atrium; LVDDd, left ventricular diastolic diameter; IVST, thickness of the intraventricular septum; PWT, thickness of the posterior wall; and RVA, right ventricular apex.
could be safely repositioned without a surgical repair. (3) The procedure could be safely performed without interrupting the antiplatelet therapy. (4) Perforations of the RV lead were equally observed for the PM leads and ICD leads. (5) We could not obtain any specific baseline characteristics or echocardiographic findings that could characterize the perforation group.

**Manifestations of lead perforations:** The clinical symptoms of lead perforations might vary among cases, from being asymptomatic to severe, such as cardiac tamponade. An increased capture threshold without any manifestation was the most common initial sign of a lead perforation in our study. The right ventricle has a low-pressure system, and, therefore, the site of the perforation might have been sealed by the perforated lead itself, and only a high threshold (especially with unipolar pacing) was observed in our cases. Most cases were asymptomatic, and imaging could play an important role in the diagnosis of lead perforations. Recording the unipolar electrograms from the distal tip of the lead can also provide information on lead perforations.

**Management during lead traction and repositioning:** Cardiac tamponade following percutaneous lead traction was observed in only one case, which was an ICD lead group and took an antiplatelet therapy and DOACs. The other 14 cases did not exhibit any tamponade or other fatal complications. This was probably due to the “self-sealing” properties of the myocardium. Just after the lead traction, the myocardium would constrict and cover the perforated site. Therefore, the incidence of cardiac tamponade during the procedure was low in our series.

The previous reports did not include subjects who were taking anticoagulation therapy or antiplatelet therapy. In our study, the DOACs were stopped before the procedure, but the warfarin and platelet therapies were continued during the procedure. Only one case who received a SAPT and DOAC had cardiac tamponade, and another case did not have a cardiac tamponade. The continuous use of antiplatelet therapy or warfarin might be safe in this procedure. In patients who are at high risk for stroke events, it could be considered to continue them on dabigatran. In the case of cardiac tamponade, idarucizumab would be useful to neutralize the effect of dabigatran, as described in the case of performing catheter ablation.

**Clinical implications:** Although RV lead perforations may be a rare complication in CIED implantations, they

### Table II. Clinical Data of Lead Perforation Patients

| No | Days from Implantation | Age | Gender | BMI | Device | Model | Lead | Clinical Findings | Diagnosis | Unipolar ST Depression | Antiplatelet Therapy | Anti coagulation | Complication |
|----|------------------------|-----|--------|-----|--------|-------|------|-------------------|-----------|---------------------|--------------------|------------------|---------------|
| 1  | 1                      | 78  | M      | 19.6| CRTD   | SJM   | Durata | ICT (0.5/0.4 → loss of capture) | NA        | NA                  | SAPT               | DOAC             | Tamponade None |
| 2  | 2                      | 77  | F      | 22.9| PM     | Biolink | Biotronik | Diaphragmatic Stimulation | –        | +                   | +                  | –                | None          |
| 3  | 4                      | 72  | M      | 19.2| ICD    | Sola   | SJM   | ICT (0.6/0.5 → 6.0/1.0) | +        | +                   | +                  | DAPT             | None          |
| 4  | 4                      | 45  | M      | 18.8| PM     | Boston | Fineline | ICT (1.2/0.5 → 7.0/0.5) | +        | NA                  | +                  | –                | warfarin None |
| 5  | 7                      | 60  | M      | 20.2| ICD    | SJM   | Durata | ICT (0.25/0.5 → 3.25/0.5) | NA        | +                   | SAPT               | None             | None          |
| 6  | 7                      | 70  | F      | 19.6| PM     | Boston | Ingevity | ICT (0.7/0.4 → 2.7/0.4) | –        | NA                  | –                  | –                | None          |
| 7  | 7                      | 68  | M      | 27.6| ICD    | SJM   | Durata | ICT (0.5/0.4 → loss of capture) | +        | +                   | SAPT               | –                | None          |
| 8  | 7                      | 68  | M      | 26.4| PM     | Sorin | VEGA  | ICT (0.5/0.35 → 4.6/0.35) | +        | NA                  | –                  | –                | None          |
| 9  | 9                      | 69  | M      | 23.4| ICD    | Boston | Endotak | ICT (0.4/0.5 → 3.0/0.5) | +        | NA                  | SAPT               | –                | None          |
| 10 | 9                      | 76  | F      | 20.6| PM     | SJM   | Tendril | ICT (1.2/0.4 → loss of capture) | +        | +                   | –                  | –                | None          |
| 11 | 35                     | 65  | F      | 24.7| CRTD   | Medtronic | Quattro | ICT (0.25/0.5 → 3.5/0.5) | +        | +                   | –                  | –                | None          |
| 12 | 37                     | 76  | M      | 21.1| ICD    | SJM   | Durata | Pericarditis | –        | NA                  | DAPT               | –                | None          |
| 13 | 57                     | 74  | F      | 25.7| PM     | Sorin | VEGA  | ICT (1.0/0.35 → 4.25/1.0) | +        | +                   | –                  | –                | None          |
| 14 | 92                     | 84  | F      | 17.5| PM     | Medtronic | Capsule | ICT (0.5/0.4 → 3.25/0.4) | +        | –                   | SAPT               | –                | None          |
| 15 | 97                     | 62  | F      | 22.1| PM     | Medtronic | Capsule | Diaphragmatic Stimulation | –        | +                   | –                  | –                | None          |

CRDT indicates cardiac resynchronization therapy defibrillator; ICD, implantable cardioverter defibrillator; PM, pacemaker; ICT, increased capture threshold; SAPT, single antiplatelet therapy; DAPT, dual antiplatelet therapy; DOAC, direct oral anticoagulants; UCG, ultrasound cardiogram; CT, computed tomography; and NA, not available.
Figure 3. Chest X-ray (A) and computerized tomography imaging (B) showing the perforating ventricular lead was located in the thoracic cavity (arrowhead).

Table III. Details of the Right Ventricular Lead Model and the Number of Defective Leads

| LED Model                  | Perforation group (n = 15) | Non-perforation group (n = 1344) |
|----------------------------|-----------------------------|----------------------------------|
| PM leads                   | 8                           | 965                              |
| Biotronik (Dextrux 4136, Solia S, Safio S, Setox SR, Setrox S, SielloS) | 1 | 102 |
| Boston Fineline II (4456, 4457, 4470, 4471, 4479) | 1 | 61 |
| Boston INGEVITY MRI        | 1                           | 87                               |
| Medtronic Capsure 5038S    | 1                           | 1                                |
| Medtronic Capsure Fix NOVUS 5076 | 2 | 106 |
| Medtronic Capsure Fix 5086 MRI | 2 | 84 |
| Medtronic Select secure 3830 | 3 | 20 |
| SJM Tendril (1688T, 1688TC, 1888TC, 2088TC, MRI) | 1 | 465 |
| Sorin BIFLEX RF46D         | 2                           | 3                                |
| Sorin VEGA                 | 2                           | 34                               |
| Vitatron Crystal line      | 1                           | 2                                |
| ICD leads                  | 7                           | 379                              |
| Biotronik Linox Smart S    | 1                           | 1                                |
| Biotronik Linox Smart ProMRI S DX | 13 | 13 |
| Biotronik Plexa ProMRI     | 11                          |                                   |
| Biotronik Protego Pro MRI  | 28                          |                                   |
| SJM Durata (7120, 7121, 7122) | 5 | 123 |
| SJM Riata (1581, 1591)     | 5                           | 123                              |
| SJM Riata Optim (7020, 7021, 7031) | 4 | 12 |
| Guidant Endotak Endurance EZ (0154, 0155) | 3 | 3 |
| Boston ENDOTAK RELIANCE (SG0181, 0184, 0185, 0283, SG 0292, SG 0293, G0295, G0296) | 1 | 56 |
| Boston RELIANCE 4 Front    | 20                          | 50                               |
| Medtronic Sprint Fidelis 6949 | 4 | 4 |
| Medtronic Sprint Quattro (6935, 6947) | 1 | 74 |
could be potentially life threatening. However, a safe procedure for resolving lead perforations has been unclear. Operative mortality and complication risk for all major cardiovascular operations were 1.5%-6.0% and 2.4%-8.4%, respectively. Therefore, the percutaneous procedure would be safer than an operation. Our results showed that percutaneous simple lead traction would be feasible and effective in the Japanese population. Our study also suggested that antiplatelet therapy did not have to be stopped before the procedure if the patients were not taking anticoagulation therapy.

**Study limitations:** Most of the leads in this study were active fixation leads. Therefore, we could not compare active fixation and passive fixation leads. We studied the safety of simple lead traction for only ventricular leads, and not for the atrial leads. Hence, the safety and effectiveness of simple lead traction for atrial lead perforations were unknown.

**Conclusions**

RV lead perforations are a relatively rare complication of CIED implantations. Percutaneous simple lead traction and repositioning of the perforated lead with cardiac surgery backup were feasible and effective if the patients did not receive anticoagulants.

**Disclosure**

**Conflicts of interest:** All authors declared no conflict of interest associated with this study.

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