Should they stay, or should they go: Do we need to remove the old cardiac implantable electronic device if a new system is required on the contralateral side?

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BACKGROUND Ipsilateral approach in patients requiring cardiac implantable electronic device (CIED) revision or upgrade may not be feasible, primarily due to vascular occlusion. If a new CIED is implanted on the contralateral side, a common practice is to explant the old CIED to avoid device interaction.

OBJECTIVE The purpose of this study was to assess a conservative approach of abandoning the old CIED after implanting a new contralateral device.

METHODS We used an artificial intelligence algorithm to analyze postimplant chest radiographs to identify those with multiple CIEDs. Outcomes of interest included device interaction, abandoned CIED elective replacement indicator (ERI) behavior, subsequent programming changes, and explant of abandoned CIED. Theoretical risk of infection with removal of abandoned CIED was estimated using a validated scoring system.

RESULTS Among 12,045 patients, we identified 40 patients with multiple CIEDs. Occluded veins were the most common indication for contralateral implantation (n = 27 [67.5%]). Fifteen abandoned CIEDs reached ERI, with 4 reverting to VVI 65. One patient underwent explant due to device interaction, and 2 required device reprogramming. Of 32 patients with an implantable cardioverter-defibrillator, 8 (25%) had treated ventricular arrhythmia. There were no failed or inappropriate therapies due to interaction. Eighteen patients (45%) had hypothetical >1% annual risk of hospitalization for device infection if the abandoned CIED had been explanted.

CONCLUSION In patients requiring new CIED implant on the contralateral side, abandoning the old device is feasible. This approach may reduce the risk of infection and concerns regarding abandoned leads and magnetic resonance imaging scans. Knowledge of ERI behavior is essential to avoid device interactions.

KEYWORDS Abandoned device; Cardiac implantable electronic device; Elective replacement indicator; Interaction; Simultaneous contralateral device

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Introduction

Cardiac implantable electronic devices (CIEDs), such as pacemakers and implantable cardioverter-defibrillators (ICDs), are established therapies for patients with arrhythmias. As patients with CIEDs live longer and new devices have become available, there has been an increase in subsequent interventions, such as lead replacement and device upgrades. The usual approach is to insert new leads from the ipsilateral side. However, this may not be feasible for some patients, primarily because of venous occlusion. Partial venous occlusion occurs in up to 40% of transvenous devices,[1] with estimates of total occlusion ranging between 10%[2,3] and 26%.[4] If the venous system is occluded, treatment options include complex extraction/reimplantation on the same side or implant of a new CIED system on the contralateral side. If the latter option is chosen, a common practice is to remove the previous pulse generator on the occluded side while abandoning the leads. However, this carries a significant risk of infection,[5] as well as concerns regarding safety of magnetic resonance imaging (MRI) scans in those with abandoned leads.[6] Alternatively, the old pulse generator could simply be abandoned with appropriate programming designed to minimize interaction with the new contralateral device. To date, there is only 1 limited (10 patients) case series outlining the feasibility of this approach.[7] There are no large-scale, long-term studies investigating the safety and potential interaction between multiple devices. In this study, we sought to report outcomes following abandonment and

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KEY FINDINGS

- When a new cardiac implantable electronic device (CIED) system is required on the contralateral side, abandoning the old device *in situ* is a viable option. Benefits include reducing the risk of infection and avoiding the invasive procedure of device explantation.
- In the largest study to date with the longest follow-up, we demonstrate that the approach of abandoning the old CIED is safe for pacemakers and implantable cardioverter-defibrillators.
- It is important to be aware of and anticipate the elective replacement indicator behavior of an abandoned device. This can help inform appropriate programming changes on both the abandoned and the new devices to prevent device interaction.

placement of a contralateral CIED system in a consecutive series of 12,045 patients implanted in a single center over 12 years.

Methods

We identified patients with more than 1 chronically implanted CIED with a 2-step process. In step 1, all patients who underwent CIED implant at the University of Ottawa Heart Institute between December 1998 and September 2020 were extracted from our device clinic database (Paceart, Medtronic Inc, Minneapolis, MN). In step 2, postoperative chest radiographs were then analyzed using artificial intelligence (AI)-based algorithm to identify all patients who had radiographic evidence of more than 1 CIED system.

We used an automated script based on the Pynetdicom library (Version 1.5.7) to extract chest radiographs directly from the Picture Archiving and Communications System (PACS) hosted at The Ottawa Hospital. (The scripts are made available at https://github.com/therlaup/pydicom-batch.)

The CIED detection algorithm was developed using the TensorFlow Object Detection API.[8] We used the Faster R-CNN with the Resnet-152 model[9] with publicly available weights pretrained on the COCO 2017 dataset.[10] The trained model was then applied to detect CIEDs on all chest radiographs. Cases identified by this algorithm were included in the study if they had routine postprocedure device follow-up at our clinic.

Outcomes

The outcomes of interest were device–device interactions, subsequent changes in device programming, elective replacement indicator (ERI) behavior of the abandoned device, and removal of any of the devices at follow-up. In addition, we estimated the theoretical risk of infection if the previous pulse generator had been explanted while abandoning the leads, by calculating Prevention of Arrhythmia Device Infection Trial (PADIT) scores. This score is derived from 5 independent predictors of device infection in the recent PADIT trial and estimates the 1-year hospitalization rate for CIED infection.[11]

The methods comply with the principles of the Helsinki Declaration. The study protocol was approved by the Ottawa Health Science Network Research Ethics Board (OHSN-REB). As this was a quality improvement project, the need for patient consent was waived.

Results

Patients

Within the study period, 12,045 patients underwent CIED implant (Figure 1). The AI algorithm identified 51 patients with more than 1 device. Six patients were excluded because the implanted device was not eligible (3 patients had neurological stimulators, 1 had a temporary pacemaker wire, and 2 had implantable loop recorders). We also excluded 5 additional patients who did not have a routine follow-up at our device clinic. Overall, 40 patients were included in the analysis.

Baseline characteristics are listed in Table 1. Average patient age was 70 ± 14 years; 10 patients (25%) were women. The most common indication for a second device implant at a different site was occluded veins (n = 27 [67.5%]). Other reasons were a dialysis line, multiple leads, and the need for cancer radiation therapy to the original side. Average time between the original implant and a new contralateral device implant was 4.8 ± 3.0 years. Characteristics of the abandoned and new devices are listed in Table 2. Among the 40 patients, the abandoned device was a pacemaker in 22 (55%) and an ICD in 18 (45%). The new device was a pacemaker in 8 patients (20%) and an ICD in 32 (80%). A cardiac resynchronization therapy (CRT) device was implanted in 19 patients (47.5%).

Outcomes

Overall follow-up time for the study was 4.0 ± 3.3 years. Over this period, 15 of the abandoned devices (37.5%) reached ERI. The details of these 15 patients are given in Supplemental Table S1. Four were Medtronic pacemakers that self-reverted to VVI 65 at reaching ERI; the lower rate was hard-programmed and could not be adjusted. This caused interference with CRT pacing in 1 patient as the abandoned device had not been programmed to minimal output. This reduced the percentage of biventricular pacing and was managed by explant of the abandoned device. In the second patient, the abandoned device displayed unipolar ventricular lead capture despite minimum output settings, which required the new device to be programmed at a rate greater than the abandoned device. In the third patient, minimal output settings prevented capture by the abandoned device (Figure 2). This allowed the new device to be programmed with a lower rate < 65 bpm (Figure 3). Because ERI had been reached in the fourth patient before implantation of the new device, the abandoned device was allowed to pace in VVI 65 until the end of life.

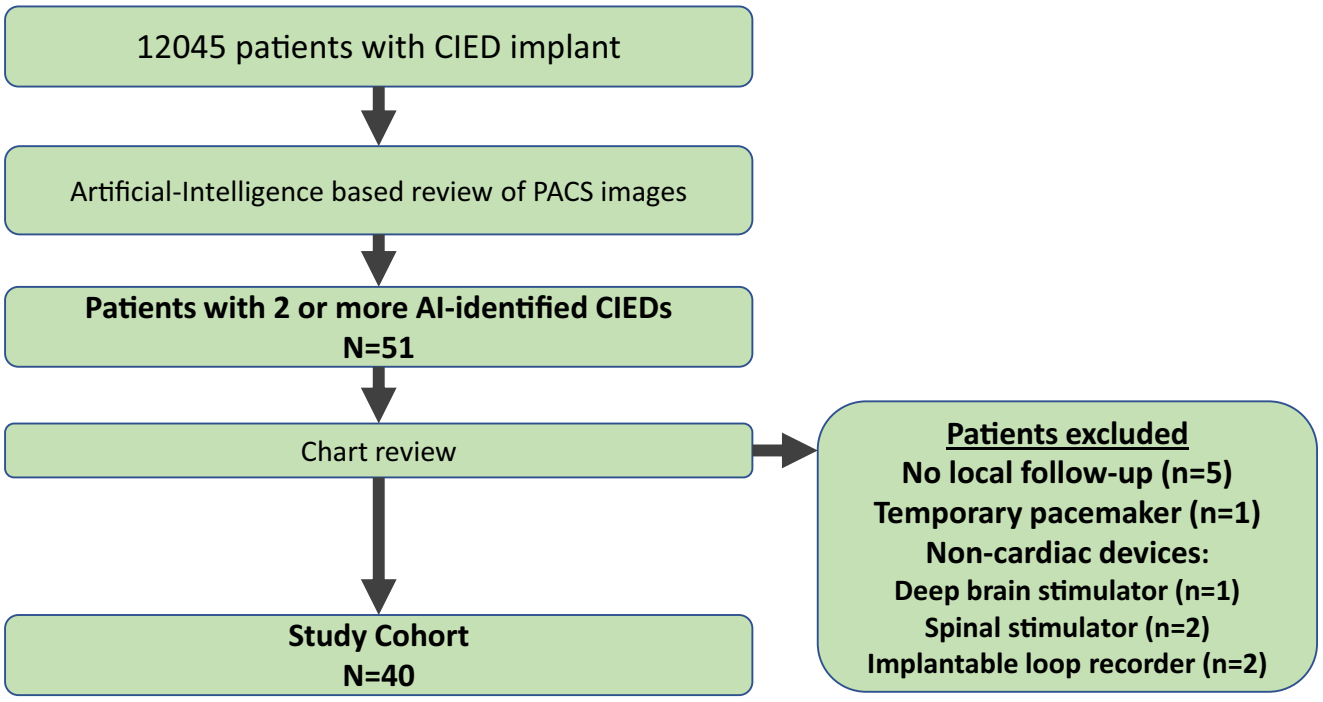

Figure 1 CONSORT diagram of patient screening and study cohort. AI = artificial intelligence; CIED = cardiac implantable electronic device; PACS = Picture Archiving and Communications System.

The remainder (11/15) did not display ERI behavior (1 Medtronic pacemaker, 2 Boston Scientific [Marlborough, MA] pacemakers, 7 Medtronic ICDs, and 1 Boston Scientific ICD).

Twenty-five percent of patients (10/40) subsequently had removal of the abandoned CIED. The reasons include device interaction (n = 1); prophylactic removal to avoid interaction with a new CRT system (n = 1; by clinician discretion, as the abandoned device was nearing ERI); severe tricuspid regurgitation leading to removal of all devices (n = 1); upgrade of the new ICD to CRT using one of the abandoned leads (n = 1); and patient request due to discomfort (n = 2) or audible ERI tones (n = 1). In the remaining case, the reason for removal was not documented.

Of the 32 patients with an ICD, 8 (25%) had ventricular arrhythmias that were successfully treated by the new device. There were no failed or inappropriate therapies due to device–device interaction in any patients.

There were no pocket infections on the side of the abandoned device. We did not observe any bilateral occlusion, and there were no cases of superior vena cava syndrome.

Estimated risk of infection if the abandoned device had been removed

The average PADIT score was 4.5 ± 2.2. Eighteen of 40 patients (45%) had a score ≥5, corresponding to a hypothetical >1% annual risk of hospitalization for CIED infection if explant of the old CIED was performed while abandoning the old leads.[11]

Discussion

In this single-center study, we describe long-term follow-up for 40 patients with an abandoned CIED system (both pulse generator and leads) at the time of new CIED implant to the contralateral side. Fifteen patients (37.5%) reached ERI on their abandoned device; 4 exhibited ERI behavior, requiring reprogramming in 2 patients and explant of the abandoned

Table 1 Baseline clinical characteristics and device details of the 40 patients included in study analysis

Female	10 (25)
Age (y)	69.7 ± 13.8
Duration between initial implant and new device implant (y)	4.8 ± 3.0
Follow-up duration after abandonment (y)	4.0 ± 3.3
Diabetes	7 (17.5)
Heart failure	32 (80)
Chronic kidney disease (eGFR <30 mL/min/1.73 m^2)	7 (17.5)
Estimated PADIT score if the abandoned device had been removed	4.5 ± 2.2
Device reached end of life	15 (37.5)
Eventual device explant	10 (25)
Indication for implant to a different site	
Occluded veins	27 (67.5)
Unknown/not recorded	8 (20)
Other*	3 (7.5)
Patient preference	2 (5)

Values are given as n (%) or mean ± SD.

eGFR = estimated glomerular filtration rate; PADIT = Prevention of Arrhythmia Device Infection Trial.

*Need for dialysis line; presence multiple leads; need for cancer radiation therapy to the original side.

Table 2 Characteristics of abandoned and new devices in the 40 study patients

	Abandoned device	New device
Site		
Right subclavicular	8 (20)	31 (77.5)
Left subclavicular	31 (77.5)	9 (22.5)
Abdominal	1 (2.5)	0
Device type		
Pacemaker	22 (55)	8 (20)
ICD	18 (45)	32 (80)
Single chamber	22 (55)	12 (30)
Dual chamber	17 (42.5)	9 (22.5)
CRT	1 (2.5)	19 (47.5)
Brand		
Boston Scientific	5 (12.5)	3 (7.5)
Medtronic	33 (82.5)	37 (92.5)
MicroPort	1 (2.5)	0
Biotronik	1 (2.5)	0

Values are given as n (%).

CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator.

CIED in 1 patient. The remainder (36/40 [90%]) did not show any device interaction.

To our knowledge, this is the largest cohort study examining the safety of abandoned CIEDs. The only previous study examining abandoned devices followed 10 patients who had a new pacemaker system.[7] No ICDs were included, and no devices reached ERI during follow-up. We demonstrate a high rate of interaction-free survival in 39 40 patients (97.5%) over a median of 4 years of follow-up, with only 1 patient requiring explant for device interaction. In retrospect, this was unnecessary and likely avoidable, as there was no trial of programming the old device to minimum output or setting the new device to a higher lower rate limit.

Device behavior at battery depletion usually is predictable. ICDs do not change pacing parameters at ERI; antitachycardia therapies remain enabled. Table 3 summarizes ERI behavior of pacemaker devices. According to modern device manuals, at ERI, Biotronik (Lake Oswego, OR) pacemakers decrease the rate by 4.5%–11% and change from dual-chamber to single-chamber mode.[12] Modern Boston Scientific devices do not change behavior at ERI but revert to single-chamber pacing at a lower rate of 50 bpm at end of life.[13] Modern St. Jude (Abbott Laboratories, Abbott Park, IL) devices prolong the minimum pacing interval by 100 ms at ERI.[14] Medtronic devices revert to VVI 65 at ERI.[15] In general, CRT-pacemakers behave similarly to dual- and single-chamber pacemakers at ERI. In our study, we observed Medtronic device VVI 65 behavior at ERI in 4 patients. This caused device interaction (loss of CRT pacing) in 1 patient despite the abandoned device being programmed to minimum output. An alternative approach would be to increase the new device's lower rate limit. In 2 other patients, programming changes mitigated device interaction; the abandoned device was set to minimum output in 1 patient and did not capture. The second patient had the new device lower limit set to 70 bpm to suppress pacing from the abandoned device.

The 2 patients who had a Boston Scientific pacemaker that reached ERI did not exhibit any change in lower rate limit and thus did not cause any interaction. As expected, the abandoned ICDs did not cause any pacing interaction.

Therefore, knowledge of an abandoned CIED model's behavior at ERI is critical and may allow clinicians to program devices appropriately and help avoid interaction, especially if the abandoned device continues to capture at minimum output. As shown in Table 3, some devices increase the lower rate limit at ERI and others decrease it. Regardless of the abandoned device's ERI lower rate limit, a combination of checking for adequate sensing on the abandoned device and programming the new device to a higher lower-rate limit will prevent overpacing. The abandoned device should also be set to minimum output to avoid capture, further preventing overpacing; however, this may not be possible if the pacing threshold is very low.

There are rare reports of erratic behavior of pacemakers at ERI,[16] but we did not observe any erratic or runaway phenomena in our cohort. However, knowledge of this rare phenomenon is important to inform shared decision making.

The first reason for abandoning devices is to reduce the risk of infection, which is higher with recurrent procedures on the same device pocket.[17] Infection is one of the most significant complications of the device implant procedures and causes extensive mortality and morbidity.[18] The calculated PADIT scores showed moderate or greater risk for nearly half of patients in our study, corresponding to >1% theoretical risk of CIED infection requiring hospitalization if the old

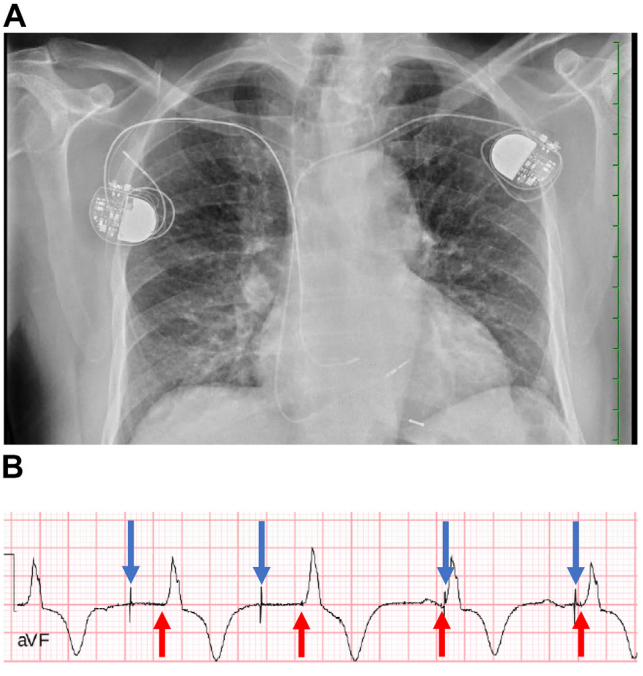

Figure 2 **A:** Chest radiograph of an abandoned device at ERI, on the patient's right side. An abandoned lead is seen as well. **B:** Electrocardiogram. *Blue arrowheads* indicate pacing spikes from the abandoned device, ~920 ms apart (corresponding to ERI rate of 65 bpm). The third QRS is sensed, leading to delay of pacing until ~920 ms later. The abandoned device is not capturing the ventricle. *Red arrowheads* indicate spikes from the new device, which captures well. ERI = elective replacement indicator.

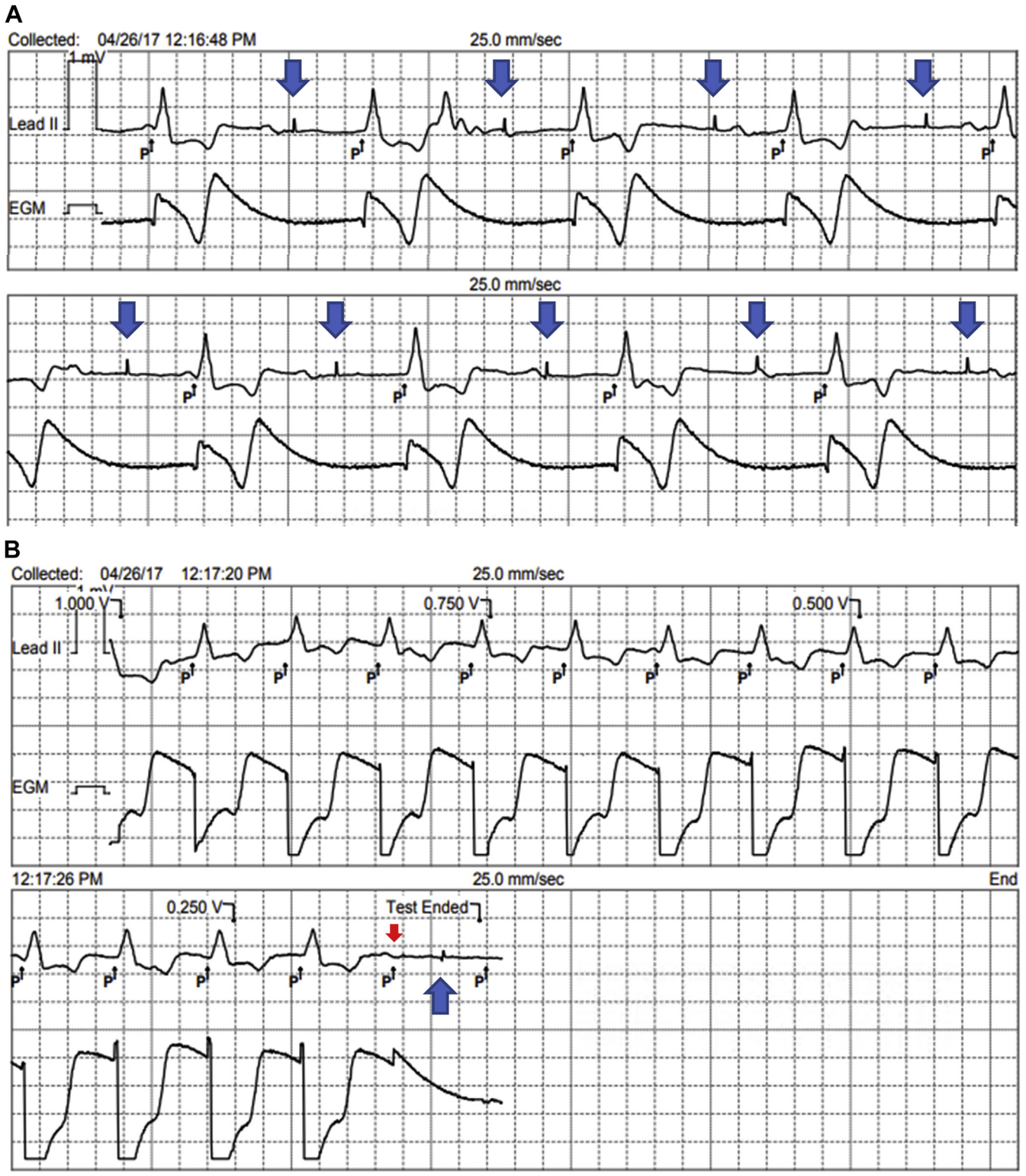

Figure 3 Device interrogation of new device with the programmer, with an abandoned device *in situ* and at ERI. **A:** When the new device is temporarily set at VVI 30 bpm, pacing spikes *(blue arrowheads)* are seen from the abandoned device, ~920 ms after each QRS, corresponding to the ERI rate of 65 bpm. There is no capture. **B:** During manual threshold testing, ventricular capture from the new device inhibits pacing from the old device. When capture from the new device is lost *(red arrowhead),* the abandoned device delivers a pacing spike at cycle length ~920 ms (65 bpm), with ventricular noncapture. These 2 maneuvers demonstrate normal sensing of the abandoned device as well as appropriate programming of the output settings to below threshold to ensure noncapture. This combination helps ensure no overpacing occurs. EGM = electrogram; ERI = elective replacement indicator.

Table 3 Summary of device behavior at ERI in pacemakers by major manufacturer

	Behavior at ERI		
Brand	Mode	Rate	Features disabled
Medtronic*	VVI	Set rate (65 bpm) or programmed rate decrease (7%–10%)	Hysteresis Sleep function ventricular capture management Atrial and ventricular sensing assurance EGM/episode/diagnostic data collection
Vitatron*	VVI	Set rate (65 bpm) or programmed rate decrease (10%–20%) or increased R-R interval (100 ms)	Rate response Post-PVC response Flywheel mode EGM range PVC-synchronous Astim Tachycardia fallback rate AF prevention therapies Ventricular rate stabilization Therapy advisor
Boston Scientific†	No change at ERI; VVI at EOL	No change at ERI; 50 bpm at EOL	
Guidant‡	VVI	Set rate (65 bpm) or programmed rate decrease (11%–20%)	Automatic capture Rate response
St. Jude§	No change	Increased R-R interval (100 ms)	Rate sensor NIPS test AF suppression
Biotronik¶	Single or dual chamber, depending on programmed mode	Programmed rate decrease (4.5%–11%)	Atrial pacing Rate adaptation Atrial and ventricular capture control Atrial overdrive pacing EGM recordings Rate hysteresis Night program Rate fading Statistics Home monitoring Ventricular pacing suppression
ELA Medical (MicroPort)‖	VVI	Set rate (70 bpm)	Rate response Smoothing Rate hysteresis

AF = atrial fibrillation; EGM = electrogram; EOL = end of life; ERI = elective replacement indicator; NIPS = noninvasive programmed stimulation; PVC = premature ventricular contraction.
*Medtronic Inc., Minneapolis, Minnesota, United States
†Boston Scientific, Marlborough, Massachusetts, United States
‡Maastricht, The Netherlands
§Abbott Laboratories, Abbott Park, Illinois, United States
¶Lake Oswego, Oregon, United States
‖Arvada, Colorado, United States

device was explanted while abandoning the leads. In the follow-up period, 30 of 40 patients (75%) did not undergo an explant of the abandoned device; therefore, the risk of infection was reduced in these patients.

A second rationale concerns the safety of abandoned leads if patients subsequently undergo MRI scans if only the old pulse generator is removed. *In vitro* studies have shown that tips of abandoned leads can heat by 10°C[19] to 30°C[20]; when directly compared, leads attached to devices have up to 96% less lead heating.[20] Although small limited studies have shown no adverse effects,[21,22] larger studies are lacking. A Heart Rhythm Society consensus statement[6] and European Society of Cardiology guidelines[23] acknowledge the risk of disconnected leads causing thermal injury; hence, leaving an abandoned CIED connected to leads could reduce the chance of adverse events in these situations.

Even with our considerable experience, substantial knowledge translation is required regarding this approach. For example, a patient who did have device interaction may have avoided explant with programming. A second patient had a prophylactic device explant when device programming would have prevented the need for explant. Finally, electrocardiographic appearances with noncapture (Figure 2) may lead to concerns unless the etiology is correctly identified.

Current society guidelines do not provide guidance when a patient has a pre-existing CIED and a contralateral device is required. The 2018 American College of Cardiology/American Heart Association guidelines[24] suggest that for patients

who no longer have an ongoing indication for a pacemaker, discontinuation of therapy is an option, but no guidance on method is provided (explant vs programming therapy off). The 2021 European Society of Cardiology guidelines[23] similarly provide options for a pacemaker that is no longer indicated but do not provide recommendations. Knowledge of the behavior of CIEDs at ERI is mentioned as an important consideration to the feasibility of leaving systems *in situ.* Although a Medtronic safety statement notes that a CRT-pacemaker's VVI 65 ERI behavior may lead to loss of biventricular pacing,[25] there are no recommendations from any CIED manufacturers regarding the interaction between 2 devices when ERI is reached.

Study limitations

Limitations of our study include the small number of abandoned devices despite a large number of CIEDs implanted at our center. Although the AI algorithm was internally validated, some patients might not have been captured. Finally, there was a disproportionate number of Medtronic devices, with an underrepresentation of other companies.

Conclusion

In patients requiring a new CIED implant on the contralateral side, abandoning the old device is feasible. This approach may reduce the risk of infection and concerns regarding subsequent MRI scans. Careful attention should be paid to the ERI behavior of abandoned devices to identify the need for additional programming. All abandoned devices should be programmed with minimum output voltage and pulse width to prevent interaction with the new CIED.

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Patient Consent: As this was a quality improvement project, need for patient consent was waived.

Ethics Statement: The methods comply with the principles of the Helsinki Declaration. The study protocol was approved by the Ottawa Health Science Network Research Ethics Board (OHSN-REB).

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hroo.2022.02.005.

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