

# Feasibility study for echocardiography-guided lead insertion for permanent cardiac implantable electronic devices

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## Abstract

**Background:** Permanent cardiac implantable electronic devices (CIEDs) are traditionally implanted with the assistance of fluoroscopy. While clinically effective, this technique exposes both patients and providers to radiation which is associated with adverse health effects and represents an occupational hazard. In this study, we investigate the safety and feasibility of permanent CIED placement under the guidance of transthoracic echocardiography (TTE). There is also increasing interest in use of non-fluoroscopic options for noninvasive cardiac electrophysiologic procedures.

**Methods:** Fifteen patients consecutively consented for initial implant of CIEDs, specifically dual chamber pacemakers (DCPM) and dual chamber implantable cardioverter defibrillators (DCICDs). Patients were excluded if they had previous implants, abandoned leads, or anatomic anomalies including congenital and known persistent left superior vena cava (PLSVC). We used TTE to guide and implant atrial and ventricular leads.

**Results:** Eleven patients received DCPMs and four patients received DCICDs. The procedure duration was 49.3 min for DCICD and 52.3 min for DCPM,  $p = .807$ . The average number of right atrial lead attempts was 1.6 for DCPMs and 1.8 for DCICD,  $p = .860$ . The average number of right ventricular lead attempts for DCPMs was 2.2 and 1.0 attempt for DCICDs,  $p = .044$ . There were no complications at 90-day follow-up.

**Conclusion:** We demonstrate the feasibility of TTE-guided DCPM/DCICD implantation without use of fluoroscopy. We present this method as a safe alternative for permanent CIED placement that may reduce risk of radiation exposure and cost while maintaining safety and efficacy. No operators wore lead aprons during the procedure.

## KEYWORDS

alternative CIED placement technique, feasibility study, fluoroscopy, limited resource contexts, permanent pacemaker and ICD, transthoracic echocardiography

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## 1 | INTRODUCTION

Cardiac implantable electronic devices (CIEDs) are increasingly utilized around the world, with roughly one million pacemakers implanted each year. In the United States, more than 200,000 devices are implanted annually.<sup>1</sup> The technique for the implantation of CIEDs has evolved from thoracotomy placement to less invasive approaches with transvenous lead placement using fluoroscopic guidance. Although less invasive, the use of fluoroscopy is associated with occupational injuries including orthopedic strain due to the use of leaded aprons in electrophysiology and cardiac catheterization laboratories.<sup>2,3</sup> The fluoroscopy-guided approach predisposes patients and healthcare providers to increased radiation exposure and subsequent adverse health effects. Furthermore, the use of fluoroscopy is a limiting factor to widespread implantation of CIED in resource-limited settings. Prior studies have explored non-fluoroscopic alternatives for temporary device insertion, including electromagnetic mapping systems, ultrasound, and echocardiography in device implantation.<sup>4-7</sup>

However, there is limited data on the use of transthoracic echocardiography (TTE) in the complete insertion of dual chamber permanent pacemaker (DCPM) and dual chamber implantable cardioverter defibrillator (DCICD). In this study, we demonstrate the safety and feasibility of TTE-guided DCPMs and DCICDs implantation.

## 2 | METHODS

### 2.1 | Patients

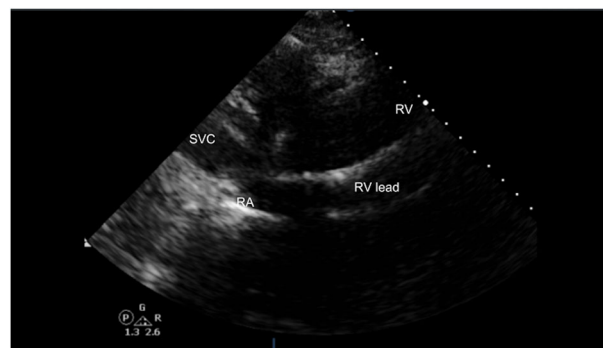
We enrolled a convenience sample of 15 consecutively consented patients with indications for DCPM and DCICD implants between August 2017 and July 2018. Local institutional review board approval was obtained. Consistent with the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for pacemaker implantation,<sup>8</sup> patients were included in the study if they were candidates for the initial implant of PPM/ICD at the time of enrollment and were amenable to follow-up in an outpatient setting for 90 days after the procedure. Patients were excluded from the study if they had previous implants, abandoned leads or anatomic anomalies including congenital or persistent left superior vena cava (PLSVC). Inclusion and exclusion criteria are summarized in Table 1. We used TTE to implant right atrial (RA) and right ventricular (RV) leads.

### 2.2 | Procedure

The implanting physician performed the procedures with the assistance of the clinical support staff and an echocardiography technician. Lead aprons were not used during the procedures. Leads were implanted with standard subclavian or axillary access techniques using anatomic landmarks. After obtaining transvenous access, normal saline was injected through the side port of the sheath to confirm echocardiographic visualization of the superior vena cava (SVC) and RA

**TABLE 1** Inclusion and exclusion criteria

Inclusion
<ul style="list-style-type: none"> <li>• Patients currently indicated for initial implant of PPM and ICD</li> <li>• Willingness to follow-up in outpatient setting for 90 days post-procedure</li> </ul>
Exclusion
<ul style="list-style-type: none"> <li>• Previous implant or abandoned leads</li> <li>• Anatomic anomalies, including congenital or persistent left superior vena cava</li> <li>• Active infection</li> </ul>

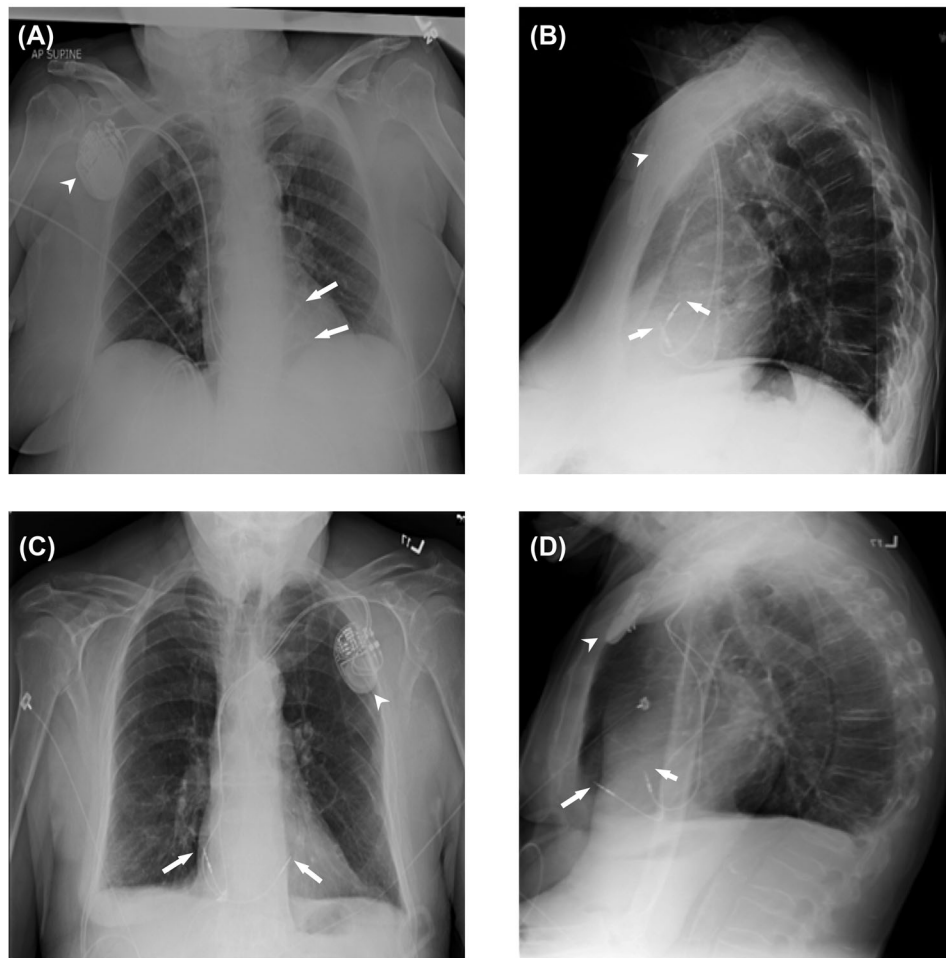


**FIGURE 1** Transthoracic echocardiogram with visualization of leads in subcostal view. RA = right atrium; RV = right ventricle; SVC = superior vena cava [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

and RV chambers. The presence of saline contrast in the RA and the SVC allowed exclusion of PLSVC (videos S1-S2).

The echo technician was not scrubbed and stood on opposite side of the operator and obtained images under the sterile drape. The acquired TTE images were used to guide the placement of the leads; subcostal, modified apical four chamber, and parasternal views were obtained (Figure 1, videos S3-S4). The leads were introduced through the sheaths and visualized by echo traversing the tricuspid valve annulus to the RV. Before the deployment of the lead helix, recording was obtained using the pacing system analyzer (PSA) to demonstrate adequate R wave sensing. Pacing was performed before the deployment of the active fixation helix to demonstrate adequate electrode-tissue interface. This technique was used to ascertain tissue contact before the deployment of the screw. The ability to pace at a threshold of 2 volts (V) or less established adequate electrode tissue contact before the deployment of the helix screw. The screw was deployed and the current of injury was recorded. With adequate current of injury and fixation of the lead, final parameters were obtained. Additional slack was applied to visualize part of the lead in the posterior portion of the RA and the lead was secured with suture ligatures.

The RA lead was deployed and was best visualized from the subcostal and parasternal long axis views allowing the localization of the RA appendage (RAA). The RAA is best visualized by initially visualizing the inferior vena cava with the probe rotated counterclockwise



**FIGURE 2** Postoperative chest radiograph demonstrating placement of both right-sided and left-sided leads (arrows) and devices (arrowheads). A = right AP (anteroposterior), B = right lateral, C = left AP, D = left lateral

and tilted cephalad to visualize the SVC. The RAA usually appears as an elongated or rectangular structure anterior and medial to the SVC on subxiphoid echo view (video S5). With the lead traversing from the SVC into the RA, the J-stylet was applied inside the lead and there was clockwise rotation of the lead tip with visualization into the RAA. Adequate electrode-tissue interface was ensured. After RA capture, adequate electrode-tissue interface was re-demonstrated in the same manner. The screw was deployed, and the J-stylet was removed with rapid withdrawal per standard technique. In patients with atrial fibrillation, p wave amplitude greater than 1.2 millivolts (mV) was accepted as adequate tissue contact. Adequate slack was demonstrated by visualization of the J-loop inside the RA and the body of the RV lead in the back wall of the RA (video S6). The leads were secured to the fascia and echocardiogram images were obtained. There were no pericardial effusions. Lead parameters were re-tested at the conclusion prior to attaching the pacemaker generator. The final lead location and lead slack were verified and documented with post-procedure fluoroscopy and chest radiograph (CXR) as per protocol design (Figure 2).

We documented the total implant time required for the PPM and ICD systems. Procedure duration was defined as the time of initial skin incision to skin closure. Implant criteria for adequate sensing and adequate threshold was defined as (1) threshold of less than 1 V at 0.4 or 0.5 ms, p wave amplitude more than 1 mV, or R wave amplitude of more than 5 mV; (2) stable impedance measurement; and (3) a current of injury amplitude deflecting positive current of injury recording after the active fixation in the RA and RV. If all three criteria were not satisfied, the lead was repositioned. All the leads were targeted for septal pacing with lower to mid septal positioning for DCICD and high to mid septal positioning for DCPM (video S7). We used septal positioning due to lower incidence of cardiac perforation compared to apical positioning within our institution and due to lower mortality compared to apically placed leads.<sup>9,10</sup>

All lead parameters were documented at implant and at 90-day follow-up. Defibrillation thresholds testing (DFTs) were performed in the ICD subpopulation to provide a confirmatory step for ascertaining satisfactory performance of the implanted device. A minimum of 10 joules safety margin was achieved in all four DCICDs. We utilized the

**TABLE 2** Patient demographic data

Case	Age	Gender	Race	BMI	Indication	Device
1	77	M	W	23.7	SSS	DCPM
2	87	M	AA	21.0	SSS	DCPM
3	81	F	W	29.5	SSS	DCPM
4	84	F	W	19.5	SSS	DCPM
5	85	F	W	27.8	SSS, SB	DCPM
6	69	F	AA	27.1	HCM, SND	DCICD
7	79	M	AA	25.4	HFrEF, DCM	DCICD
8	69	M	AA	26.6	SND	DCPM
9	59	F	AA	35.7	SSS	DCPM
10	71	F	W	24.1	SSS	DCPM
11	62	M	W	27.1	SSS	DCICD
12	84	M	W	24.9	CHB	DCPM
13	61	F	AA	39.7	CHF CM SSS	DCICD
14	76	M	W	23.4	SSS	DCPM
15	74	M	AA	33.6	SSS	DCPM

Abbreviations: W, white; AA, African-American; M, male; F, female; SSS, Sick sinus syndrome; SB, Sinus bradycardia; HCM, hypertrophic cardiomyopathy; SND, Sinus node dysfunction; HFrEF, Heart failure with reduced ejection fraction; DCM, Dilated cardiomyopathy; CHF, Congestive heart failure; CHB, Complete heart block; CM, Cardiomyopathy.

**TABLE 3** Intraoperative implant parameters

	Average RA lead attempt	ATTC(v/ms)	A impedance Ohms	Average RV lead attempt	VTTC(v/ms)	V impedance Ohms	P wave amp(mV)	R wave amp(mV)
DCPM	1.6	.7/.6	774.0	2.2	.7/.5	920.9	3.7	6.1
DCICD	1.8	.6/.5	749.8	1	.5/.5	559.0	2.9	8.0

Abbreviations: Amp: amplitude, ms: milliseconds, mV: millivolts, V: volts.

5076 and/or 3830 lead for PPM implants and 6935/6935 M for ICD implants, both with the option of a passive lead.

### 2.3 | Statistical analysis

Statistical analyses were performed with SPSS (version 27, IBM Corp, Armonk, NY, United States) and R statistical software (version 3.6.0, Vienna, Austria). A Student's t-test was used for continuous variables. A  $p$ -value of  $< .05$  was considered statistically significant.

## 3 | RESULTS

Fifteen patients were enrolled, with 11 patients receiving DCPM and four patients receiving DCICDs. The average age was 74.5 years and average BMI was 27.3 kg/m<sup>2</sup>. There were no statistically significant differences between the DCPM and DCICD groups,  $p = .111$  and  $p = .389$ , respectively. Demographic data is summarized in Table 2. The average

procedure time was 52.3 min for DCPM implantation and was 49.3 min for DCICD implantation,  $p = .807$  (Figure 1). The average number of RA lead attempts was 1.55 for the DCPM procedure and 1.75 for the DCICD procedure,  $p = .860$ . For the RV lead, the average number of attempts in the DCPM group was 2.2 and one in the DCICD group,  $p = .044$ . All patients had satisfactory DFT parameters with greater than 10 Joules safety margin. Final parameters of the pacemakers and ICD groups are summarized in Table 3.

All patients underwent successful TTE-guided device implantation, confirmed with fluoroscopy and postoperative chest radiograph as per study protocol (Figure 2). In all procedures except one, chambers were accessed from the left pectoral region without need for repositioning. The only patient receiving a DCPM implant from the right pectoral region created anatomical challenges for access. In this patient, intraoperative lead dislodgment required multiple lead attempts due to poor echocardiographic window and excess lead slack. The patient also required intraoperative repositioning due to abnormal pacing and sensing thresholds. No patients required passive leads.

**TABLE 4** Average implant parameter at day 0 and day 90

	Implant parameter at day 0		Implant parameter at 90 days	
	DCPM	DCICD	DCPM	DCICD
ATTC(V/ms)	0.7/0.6	0.6/0.5	<1.0/0.5	<1.0/0.5
VTTC(V/ms)	0.7/0.5	0.5/0.5	<1.0/0.5	<1.1/0.4

Abbreviations: Atrial threshold to capture (ATTC); Ventricular threshold to capture (VTTC); V = volts, ms = milliseconds.

Additionally, three patients were in persistent atrial fibrillation at the time of implant, which did not permit the utilization of the capture technique. Instead, for these patients, we determined adequate lead attachment with surrogate measures of P-wave amplitude greater than 1.2 mV. These patients were planned for cardioversion after the procedures.

At the time of hospital discharge and at 90-day follow-up, we did not observe any other complications, including pneumothorax, pericardial effusion, or lead dislodgment. At 90-day follow-up, all the devices were noted to be functioning normally with stable sensing and thresholds. Average implant parameters at day 0 and day 90 are recorded in Table 4.

## 4 | DISCUSSION

This case series demonstrates the safety and feasibility of TTE-guided implantation of DCPM and DCICDs. The average procedure time was comparable to historical procedure duration of 45–75 min at our institution. To our knowledge, limited data exists on the use of TTE in the insertion of permanent devices, and few studies have demonstrated the feasibility of TTE in the insertion of DCPMs and DCICDs. The use of fluoroscopy is disadvantageous for both patients and operators as there are several adverse effects of radiation exposure, including malignancy and hematological, dermatologic, reproductive, and immunologic disorders.<sup>2,3</sup> Regarding the ergonomic and orthopedic effects of radiation exposure and lead apron use for operators,<sup>11,12</sup> further studies will be necessary to compare benefits of TTE-guided device placement over traditional fluoroscopy. We postulate that echocardiography-guided procedures will reduce long-term radiation complications and orthopedic strain; the reduction of radiation exposure will likely also be more beneficial to pregnant women, children, and clinical staff.

In this study, no patients received passive leads reflecting the practice of our institution. We performed DFT testing to ascertain satisfactory performance of the implanted device as this was a clinical study defining a new technique, and we performed it as an additional cautionary step for the purpose of this study. In addition, one patient had an indication of hypertrophic cardiomyopathy with high-risk characteristics. We performed a careful risk benefit analysis for each patient prior to DFT testing in this study, and all had satisfactory parameters with greater than 10 Joules safety margin. While no patients in our study population had a coronary artery bypass graft (CABG), it is our opinion that for patients undergoing this procedure with prior CABG, atrial

appendage resection will not significantly alter atrial lead placement. We believe it necessary to obtain echo visualization of the anterolateral atrial wall and to assess for phrenic nerve stimulation in this location.

As a portable imaging modality, echocardiography could also be employed to facilitate temporary and permanent pacemaker implantation in intensive care units and reduce in-hospital transfer.<sup>4,6</sup> Furthermore, the use of non-fluoroscopic lead implantation for temporary pacemakers has been reported using ultrasound, computed tomography (CT), and echocardiography.<sup>4–7</sup> Subcostal echocardiograph views have been utilized in the acute, perioperative setting to guide insertion of a RV temporary transvenous pacemaker.<sup>13</sup> Intracardiac echocardiography and electroanatomic mapping have been reported in a permanent pacemaker placement of a pregnant patient.<sup>6</sup> In a case of a patient with congenital heart disease, echocardiography was used for determination of atrial capture for programming.<sup>14</sup> Our study is one the few studies in the literature that illustrates the feasibility of complete dual chamber device implantation using TTE, favored over alternative imaging techniques such as fluoroscopy and CT-guided implantation due to increased radiation exposure.

In low-resource settings, access to fluoroscopy remains a limiting factor to implantation of CIEDs. The use of TTE provides a safe, efficacious, and cost-effective alternative for the implantation of permanent leads in low-resource environments, in combat settings, and in disaster response. Avoidance of fluoroscopy may contribute to reducing the economical barrier that precludes extensive device implantation in developing countries. In a multinational study seeking to determine reasons for cardiac implant refusal, inability to pay for the procedure was cited as the most common reason for implant refusal.<sup>15</sup>

Three-dimensional (3D) echocardiography is an evolving trend in the technology of lead placement. Benefits include improved intraoperative visualization and better definition of anatomic structures. It may enable use for other pacing modalities including cardiac resynchronization therapy devices, His bundle lead placement, and leadless pacing devices. Future studies will be necessary to assess the feasibility of 3D-echocardiography-guided implantation of CIEDs. In the future, this technique may also prompt development of leads with better visualization using echocardiography or other non-fluoroscopic options. Future consideration may include transesophageal echocardiography (TEE) in intubated patients for further visualization of intracardiac structures.

Limitations of the study include the small sample size. Further study will include validation with a randomized controlled study in a larger population to evaluate procedure time between the use of TTE and

fluoroscopy and to analyze the exposure time. Furthermore, we did not assess inter-operator variability as this study was performed by a single operator with extensive CIED implant experience.

## 5 | CONCLUSION

We demonstrate the feasibility of DCPM/DCICD implantation with limited use of fluoroscopy. Echocardiography-guided device insertion may prove beneficial in procedural time reduction, improve safety, reduced risk of radiation exposure, increased quality, and cost reduction. This is a pertinent technique that can be readily implemented in certain patient populations, including pregnant patients. The utility of echocardiography has previously been described for perioperative and temporary CIED placement; here we describe use of echocardiography in permanent device placement. This method can also be scaled to resource-limited settings as well as to the bedside or other constrained environments in the setting of the ongoing COVID-19 pandemic.

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## CONFLICTS OF INTEREST

FOS received a grant from Medtronic. For the remaining authors, there are no conflicts of interest to disclose.

## AUTHOR CONTRIBUTIONS

Felix O. Sogade conceptualized and designed the study, secured funding, and provided critical revision of the manuscript. Omolade O. Sogade performed data analysis and interpretation and wrote the manuscript. Rieta N. Aben, Harry Eyituyo, Nkechi C. Arinze contributed to revision and all authors approved the article.

## DATA AVAILABILITY STATEMENT

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

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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