

Management of inadvertent lead placement in the left ventricle via a patent foramen ovale: A multidisciplinary approach



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Introduction

Cardiac devices, including pacemakers and implantable cardiac defibrillators (ICD), are increasingly used for the management of cardiac arrhythmias as well as heart failure. A rare complication of the cardiac device implantation includes inadvertent placement of a right ventricular (RV) lead in the left ventricle, which can have serious consequences including systemic thromboembolism.¹ The lead malpositioning can be discovered late, and the optimal management strategy for this under-reported complication is unclear, owing to its rarity.

We report a case of inadvertent RV ICD lead placement in the left ventricle via an aneurysmal patent foramen ovale (PFO), where the lead malpositioning was discovered several months after implantation. Utilizing a multidisciplinary team approach including cardiac electrophysiology, the structural heart team, and echocardiography, a transcatheter cerebral protection device was placed during the procedure, the lead was percutaneously withdrawn from the systemic circulation, and a new ICD lead was positioned in the right ventricle. During the same procedure, transcatheter closure of the PFO was also performed. The rationale and the steps of performing this complex procedure are discussed in this report.

Case report

A 64-year-old man with nonischemic cardiomyopathy, left ventricular ejection fraction of 20%, and left bundle branch block on the electrocardiogram with a QRS duration of greater than 150 ms was referred to our clinic after implantation of a biventricular ICD system approximately 6 months prior. Follow-up echocardiography at the outside institution had revealed inadvertent placement of the RV lead into the left ventricle via a PFO and the patient presented to our institution for further management. The patient continued to have

KEY TEACHING POINTS

- Inadvertent placement of a right ventricular lead in the left ventricle is a rare complication of cardiac device implantation that can have serious consequences, including systemic thromboembolism.
- An embolic protection device placed in the brachiocephalic artery and left carotid artery may be used to prevent systemic thromboembolism at the time of lead extraction.
- There are no clear recommendations regarding closure of patent foramen ovale (PFO) after repositioning a lead that was inadvertently placed through it. It may be beneficial in patients with aneurysmal primum atrial septum with the presence of bidirectional flow. Moreover, closure of a PFO can theoretically reduce the risk of dislodging relatively new leads.

NYHA class II symptoms and denied any symptoms to suggest stroke or transient ischemic attack (TIA). He had recently been initiated on warfarin, and his international normalized ratio was subtherapeutic. On examination, his vital signs were unremarkable, and the device incision had healed well, without any evidence of infection. A transesophageal echocardiogram (TEE) was performed that confirmed the placement of the RV ICD lead via a PFO into the lateral left ventricular endocardium (Figure 1A). There was no obvious evidence of thrombus on the lead by TEE. The septum was aneurysmal and there was bidirectional flow across the PFO. The position of the lead in the left ventricle via a PFO was corroborated on a left anterior oblique image during subsequent fluoroscopy (Figure 1B).

Given the presence of a lead in the left ventricle with subtherapeutic international normalized ratio, we decided to

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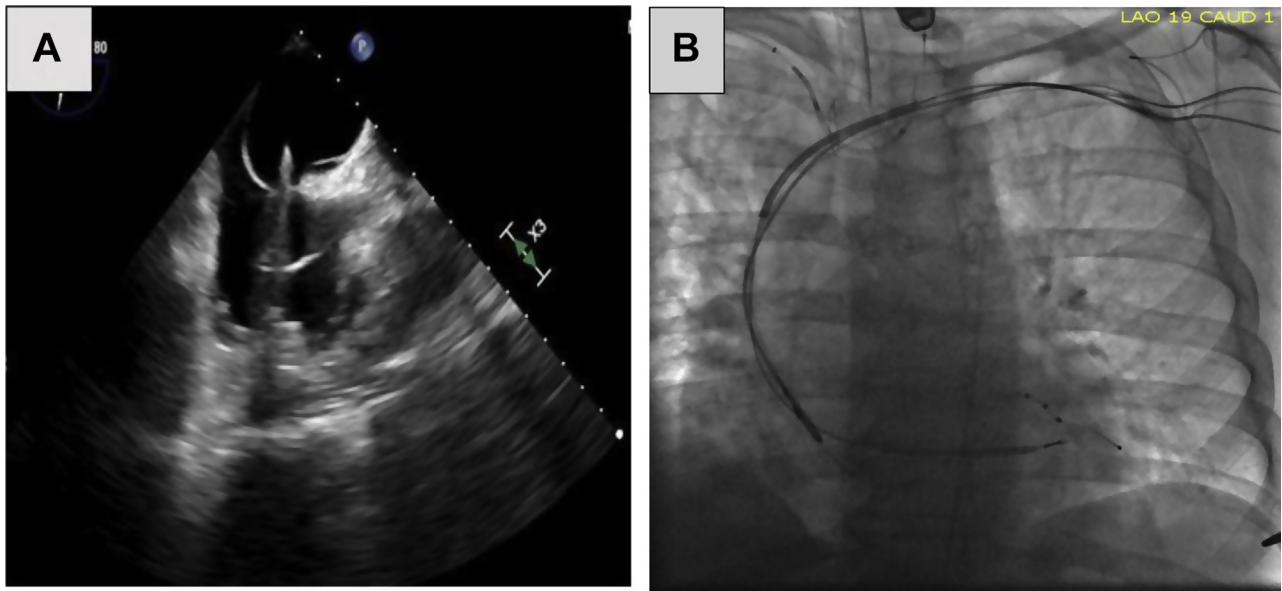


Figure 1 A: Two-dimensional transesophageal echocardiogram image showing improper placement of the right ventricular implantable cardiac defibrillator lead via a patent foramen ovale into the left ventricular endocardium. B: Fluoroscopy image prior to the start of the procedure described above showing the right ventricular lead in the area of the left ventricle.

switch the patient's anticoagulant to a novel oral anticoagulant, and he was started on apixaban 5 mg orally twice a day based on his age and renal function (which was normal). After a multidisciplinary discussion, we decided to percutaneously remove and replace the lead. Since the possibility of microthrombi/fibrinous material on the lead could not be ruled out, we decided to deploy a SENTINEL (Boston Scientific, Fremont, CA) transcatheter cerebral embolic protection device. This device has been used during transcatheter aortic valve replacement and was used here to decrease the risk of stroke related to manipulation of a systemic foreign body that could shed this potential adherent fibrinous material. Also, owing to the aneurysmal nature of the PFO with evidence of bidirectional flow that suggested a higher risk of subsequent stroke, we decided to perform PFO closure during the same procedure. The procedure was performed as follows:

Step 1: The patient was not given apixaban the night before the procedure, and a repeat TEE was performed prior to the procedure under general anesthesia. There was no evidence of any thrombi on the lead.

Step 2: Following this, radial and femoral arterial access was obtained. Heparin boluses were given to maintain activated clotting time between 250 and 300 seconds. The dual-filter transcatheter embolic protection system was then sequentially deployed—the proximal filter in the innominate artery followed by the distal filter in the left carotid artery (Figure 2A).

Step 3: After placement of the embolic protection device, an incision was made in the left pectoral area at the device site, and the device as well as leads were carefully removed from the pocket and brought onto the operative field. The RV lead was detached from the device, and after placing of a standard stylet, the lead helix was unscrewed and freed from the myocardium. The lead was then care-

fully pulled back through the PFO into the high right atrium (Figure 2B). The lead was not removed out of the circulation at this time for 2 reasons: (1) to prevent significant venotomy site bleeding with systemic heparinization; and (2) because in case of difficulty obtaining a new venous access site, the lead itself could be used to retain access (by placing a micropuncture wire within the lumen and advancing it into the systemic circulation). The latter was not necessary in the end, as additional access was easily obtained (step 5). The pocket was packed with gauze and covered with a sterile dressing until step 5. Hemostatic agents were considered in the setting of systemic heparinization but were not used, as there was adequate hemostasis.

Step 4: Using a Gore 30 mm Cardioform device (W. L. Gore & Associates, Inc, Newark, DE), PFO occlusion was performed via the femoral vein under TEE guidance (Figure 2C). Adequate position was confirmed with no evidence of color flow across the device or intra-atrial septum. The device was then locked and the delivery system withdrawn. Once the PFO occlusion was complete, the heparin was stopped, and the embolic protection device was removed. Heparin was reversed using protamine. After removal of the embolic protection device, careful examination revealed 2 small debris particles (Figure 3B).

Step 5: After gaining axillary venous access, the prior ventricular lead was explanted and a new RV lead was positioned in the RV mid-septal area under fluoroscopy, with the anatomic position confirmed on TEE (Figures 2D, 3A). The new RV lead was then connected to the device. After the device and leads were placed back in the pocket, the incision was closed in multiple layers. Hemostasis was obtained at the site of the radial artery access as well as the femoral venous access site.

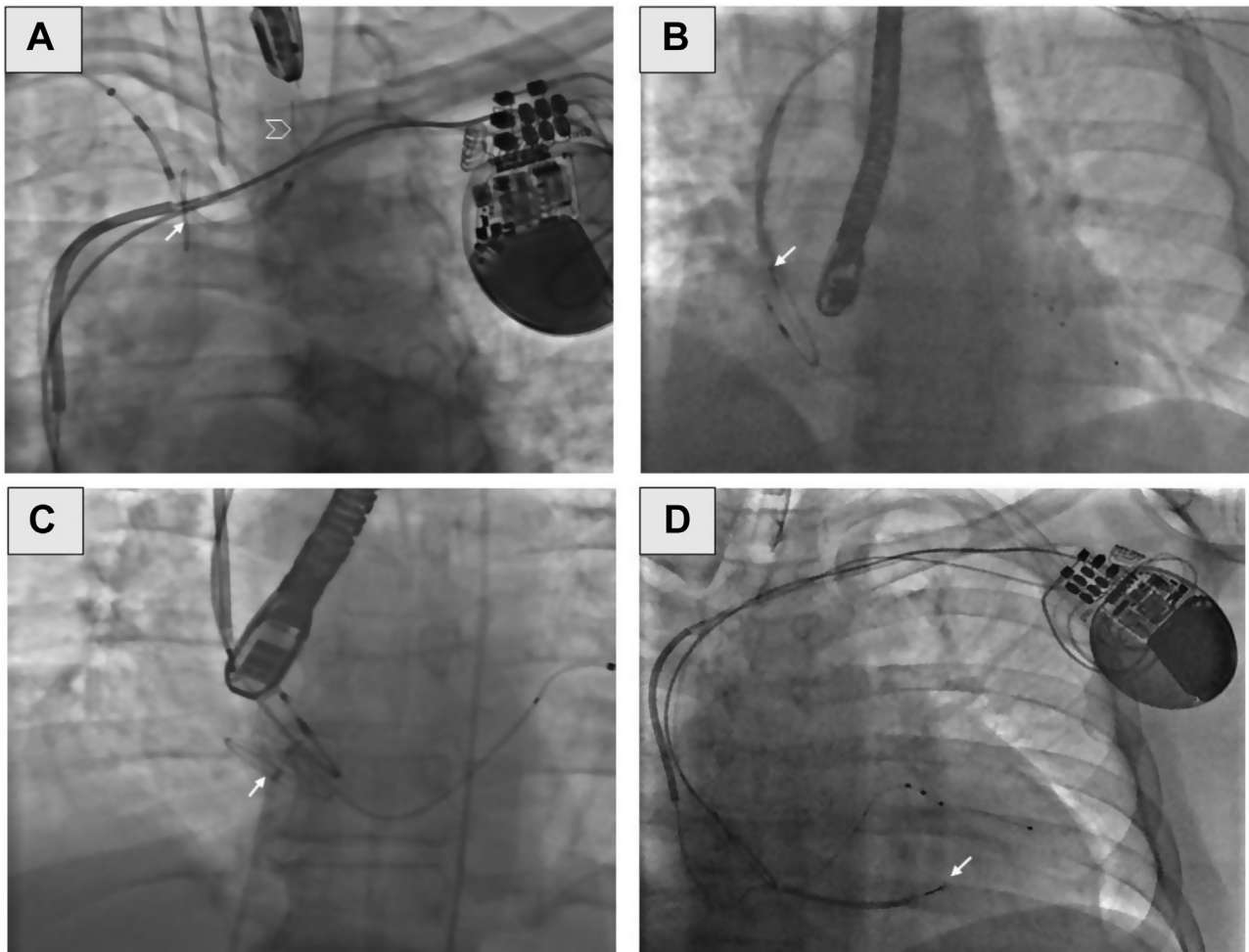


Figure 2 Stepwise approach to percutaneous left ventricular lead removal and re-implantation, with concomitant embolic protection system and patent foramen ovale (PFO) closure procedure. **A:** Placement of transcatheter cerebral embolic protection system with innominate (*arrow*) and left carotid (*arrow head*) filters. **B:** Removal of lead from the left ventricle to the right atrium (*arrow*). **C:** Closure of PFO with closure device (*arrow*). **D:** Positioning of new implantable cardiac defibrillator lead into the right ventricle (*arrow*).

The patient recovered well from the procedure and was discharged home the next day. At 1-month follow-up, the patient had normal device function and a well-healed incision site. He did not report any TIAs or stroke-like symptoms.

Discussion

Inadvertent placement of a lead in the left ventricle via a PFO that is diagnosed relatively late poses a clinical dilemma, as percutaneous removal and repositioning could result in thromboembolic complications. We report a multidisciplinary team approach to manage this complex situation with the use of a transcatheter embolic protection device to reduce the risk of stroke related to lead removal, as well as PFO closure performed in a single combined procedure.

Malpositioned RV lead into the left ventricle is a rare and likely under-reported complication of device implantation. Possible etiologies for this complication include inadvertent arterial access and placement through a PFO/atrial septal defect or ventricular septal defect. Presence of an endocardial

lead in the left ventricle poses an increased risk of systemic thromboembolism owing to the thrombogenicity of a foreign surface in the systemic circulation. Acute intraoperative recognition of left-sided lead placement through a septal defect can be safely managed with immediate withdrawal of the lead to the right atrium and proper repositioning in the right ventricle. In patients with delayed recognition (>1 year) and “symptomatic” left ventricular lead placement (such as TIA or stroke), surgical lead removal is usually performed owing to the higher risk of systemic emboli from adherent thrombus and binding scar, which would be sheared off if extraction sheaths were used to explant the lead percutaneously. Asymptomatic patients, especially if high surgical risk, can be managed with life-long anticoagulation. However, with a more “subacute” recognition (<1 year), percutaneous removal can be attempted. Consideration needs to be given to reduce the risk of thromboembolic complications, as up to 42% of patients presenting with thromboembolism had the device placed <12 months prior.² These rates are published for leads that remained in the systemic circulation

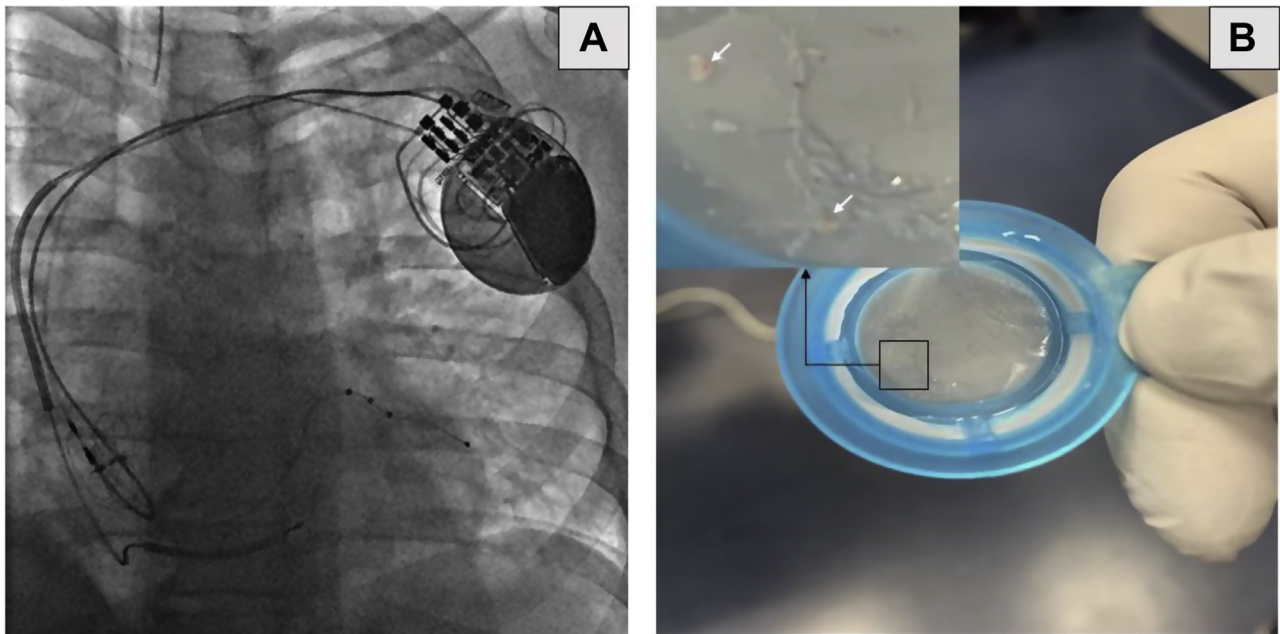


Figure 3 A: Final position of the leads with patent foramen ovale closure device in place. B: Captured embolic debris seen on the removed filters (*inset arrows*).

before the thromboembolism event. In our patient's case, the added manipulation and removal across the septum of the systemic leads further increases the risk of acute systemic embolization, especially with the high rate of adherent material in these leads waiting to embolize. We believe that this risk is high enough to warrant extra precautions that would not be relevant for right-sided leads.

There are several embolic protection devices predominantly used at the time of carotid stenting.^{3,4} The best choice of embolic protection device in this clinical situation is unknown. While individual filters can be placed in each of the 4 main arteries supplying the cerebral circulation, this would require multiple accesses, with a consequent increased risk of complications. We therefore decided to use a single device that protects 3 of the 4 arteries supplying the cerebral circulation. The device has traditionally only been used at the time of transcatheter aortic valve replacement.⁵ Most recently, Thosani and colleagues⁶ used an embolic protection device at the time of lead explant for a patient who had multiple strokes after prior improper placement of a pacemaker lead into the left ventricle from inadvertent arterial access. Unlike their case, the use of an embolic protection device in our case was considered "primary prevention" because our patient never had a stroke. Consistent with our concerns, debris was seen on the filter at the end of the procedure, and it is possible that the patient may have suffered a stroke or TIA without the use of the device.

Closure of the PFO is usually done in the setting of stroke or platypnea–orthodeoxia. There are no clear recommendations regarding closure of PFO after repositioning a lead that was inadvertently placed through it. At the time of surgical removal of inadvertently placed leads, closure of associated septal defects is usually performed. There are data to suggest that the presence of echocardiographically detected

PFO in patients with endovascular leads is associated with an increased risk of stroke/TIA.⁷ The pros and cons of simultaneous PFO closure were carefully considered using a multidisciplinary team approach and shared decision-making with the patient (Table 1). In this patient, given the high-risk features of an aneurysmal primum atrial septum,⁸ the presence of bidirectional flow across the PFO, and the nearby presence of 3 thrombogenic leads in the right atrium, we decided to close the PFO in the same procedure. There is a small risk of dislodging relatively new leads and hence the closure was performed prior to positioning the new RV lead and closing the pocket.

The biggest limitations of performing this combined procedure include the extra time taken for cerebral filter placement and PFO closure, as well as the added cost. Since most patients who suffered a stroke from inadvertent lead placement in the left ventricle did not have an obvious thrombus on TEE in prior series,² we decided that the absence of visible echogenic adherences on the lead was

Table 1 Pros and cons of simultaneous patent foramen ovale closure at the time of percutaneous repositioning of left ventricular lead

Pros	Cons
Decreases the risk of subsequent stroke associated with PFO and endocardial leads	Logistical issues (additional time, coordination between specialties)
Lead dislodgement at time of closure can be managed in the same setting/pocket access	Additional cost
Patient convenience of a single procedure	PFO closure–related risk

PFO = patent foramen ovale.

not fully reassuring, and that the time and additional device costs were well worth reducing this stroke risk during lead removal and re-placement.

Conclusions

In conclusion, we report a multidisciplinary approach to management of a lead that was inadvertently placed in the left ventricle via a PFO. A transcatheter cerebral embolic protection system was used to reduce the risk of stroke while percutaneously removing and replacing the lead, and closure of the PFO was also performed at the time of the procedure. While published and unpublished anecdotes about perioperative strokes during “simple” removal of inadvertently placed left ventricular leads suggest that our management approach is warranted in this complex clinical situation, larger studies would be required to confirm whether cerebral embolic protection with or without PFO closure meaningfully reduces the risk of stroke.

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