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RHYTHM DISORDERS AND ELECTROPHYSIOLOGY

CASE REPORT: CLINICAL CASE

First-in-Man Surgical Extravascular-ICD Implantation

Suturing the Defibrillation Lead to the Heart Wall Post Device-Related Endocarditis

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ABSTRACT

We present the first worldwide case of a hybrid surgical-percutaneous procedure involving transvenous lead extraction, concomitant tricuspid valve repair, implantation of an atrioventricular (AV) leadless pacemaker, and extravascular implantable cardioverter-defibrillator placement with suturing of the defibrillation lead to the heart wall. Multiple interventions were necessary as a result of active endocarditis, congenital complete AV block, and ventricular arrhythmia secondary prevention. (JACC Case Rep 2024;29:102424) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

HISTORY OF PRESENTATION

A 39-year-old man presented to our hospital (Centro Cardiologico Monzino, Milan, Italy) with a report of persistent fever, along with inspiratory chest pain localized in the left hemithorax, dyspnea, and a worsening cough.

LEARNING OBJECTIVES

- To demonstrate the feasibility EV-ICD placement during open heart surgery with the lead directly sutured on the free heart wall.
- To provide a possible alternative approach using the most recent pacing and defibrillation technologies to tackle this challenging and unique scenario.

PAST MEDICAL HISTORY

Despite the patient's relatively young age, his medical history included an ostium secundum atrial septal defect (ASD) with congenital atrioventricular (AV) block. Previously, the patient underwent atrial fibrillation (AF) ablation, along with dual-chamber His-bundle pacemaker (PM) implantation and ASD surgical closure. Regrettably, the patient also experienced cardiac arrest following an episode of ventricular fibrillation, necessitating an upgrade of the previously implanted PM to a defibrillator for secondary prevention, with the previously implanted

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

ASD = atrial septal defect

AV = atrioventricular

ECMO = extracorporeal membrane oxygenation

EV-ICD = extravascular implantable cardioverter-defibrillator

ICD = implantable cardioverter-defibrillator

LVEF = left ventricular ejection fraction

PM = pacemaker

RV = right ventricular

S-ICD = subcutaneous implantable cardioverter defibrillator

TEE = transesophageal echocardiography

TLE = transvenous lead extraction

TR = tricuspid regurgitation

VA = ventricular arrhythmia

His-Bundle catheter used for resynchronization therapy. On that admission, his left ventricular ejection fraction (LVEF) during admission was reduced. Five years later, the detection of a rupture in the right ventricular (RV) ICD double-coil lead prompted the placement of a new single-coil ICD lead. Approximately a decade later, a malfunction of the most recently implanted RV lead was identified. The patient underwent transvenous lead extraction (TLE) of both ICD leads and repositioning of a new ICD lead. The subsequent clinical and device follow-up was uneventful.

DIFFERENTIAL DIAGNOSIS

The differential diagnosis included endocarditis vs other infectious processes.

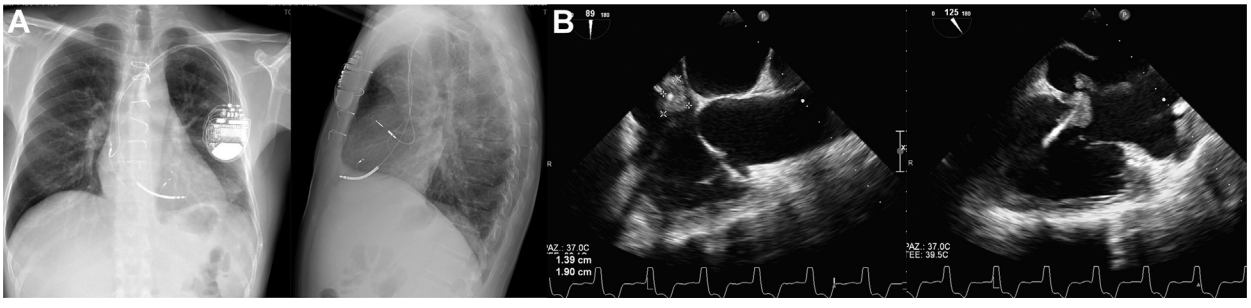
INVESTIGATIONS

On admission, the patient presented with a high body temperature (38.5 °C) and stable vital signs. A chest radiograph displayed left basal consolidation indicative of an active infection (**Figure 1A**), confirmed by subsequent chest computed tomography (Video 1). Bedside echocardiography revealed an LVEF of 50% and moderate to severe tricuspid regurgitation (TR), with 1 lead displaying hypermobility, thus raising suspicion of an active endocarditis process (Videos 2 and 3). Given the strong suspicion of cardiac device-related endocarditis, transesophageal echocardiography (TEE) was performed, revealing endocarditis-related vegetations (maximal diameter, 20 mm) adherent to 2 ventricular leads in the right heart chambers, and resulting in severe TR (**Figure 1B**, Videos 4 to 6).

MANAGEMENT

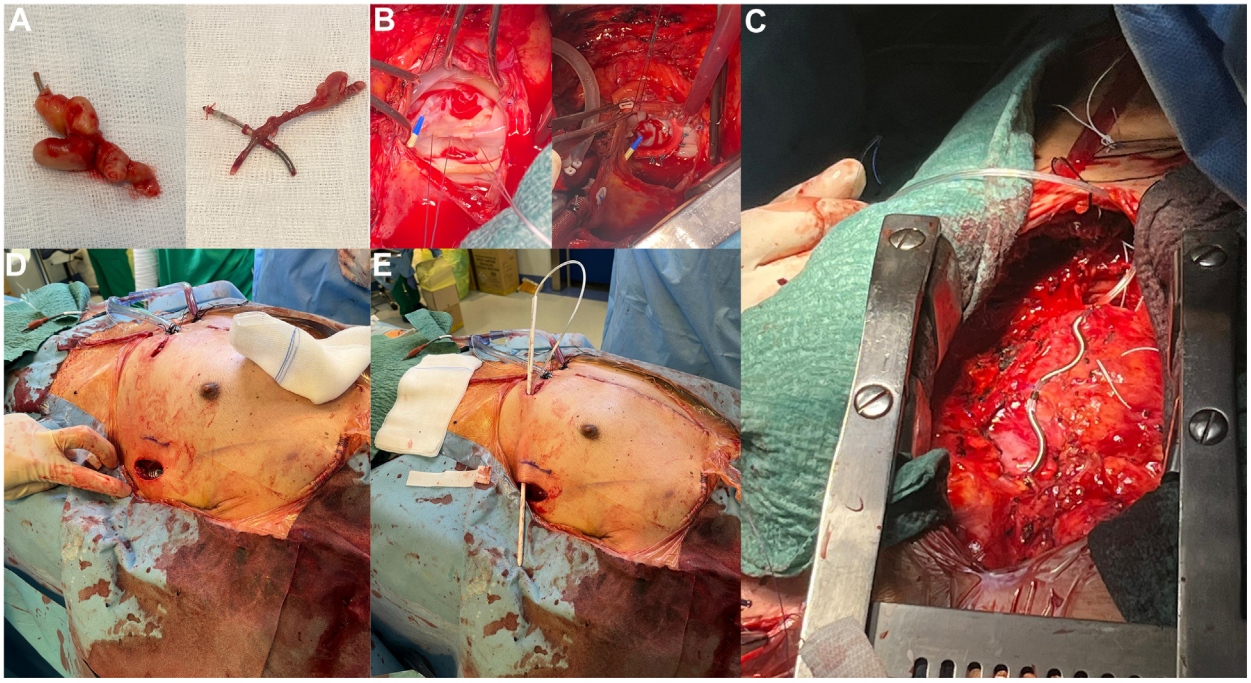
Empiric antibiotic therapy with ceftaroline and daptomycin was promptly initiated. Given the urgent need to eradicate the source of endocarditis, alongside the absolute necessity of secondary prevention for ventricular arrhythmias (VAs), TLE was scheduled and performed 14 days after initiating antibiotic treatment, after a gradual reduction in inflammatory markers. The primary goal of this procedure was to achieve lead extraction, followed by percutaneous implantation of a leadless PM and a subcutaneous ICD (S-ICD), as reported elsewhere.[1] Unfortunately, the patient was deemed unsuitable for S-ICD implantation because of failed screening in 2 of 3 vectors, and therefore the extravascular (EV) ICD (EV-ICD) was deemed a valuable alternative in this setting. The decision whether to perform tricuspid valve replacement or repair/annuloplasty had to be made intraoperatively after a thorough assessment of potential endocarditis involvement of the valve itself, involvement that could not be completely excluded by preoperative TEE. The defibrillator pocket was opened, and the leads were released from their adhesions in the deep planes. Before disconnecting the leads, a self-locking stylet was inserted into each lead. Initially, mechanical sheaths were used for lead extraction, guided by bilateral venous angiography, to facilitate lead release in the clavicular/anonymous trunk region. The single-coil lead was easily removed using this method (Video 7). However, the removal of the older atrial and His-bundle leads required additional maneuvers. A mechanical rotating dilator

FIGURE 1 Preoperative Imaging Findings



(A) Preoperative 2-projection chest radiograph reveals lung consolidation in the left lower lobe. (B) Transesophageal echocardiography highlights endocarditis-related vegetations on both devices' ventricular leads.

FIGURE 2 **Intraoperative Steps**



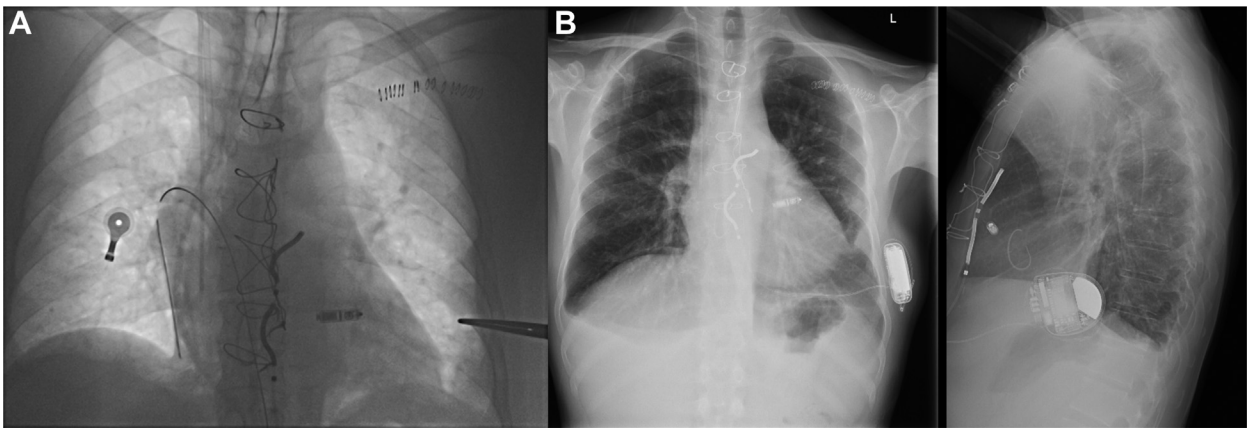
(A) Extracted atrial and right ventricular leads showing firmly adherent endocarditis-related vegetations. (B) Surgical view of the damaged tricuspid valve (left) and the same valve during posterior leaflet folding, anterior septal commissure closing, new anterior leaflet chordae tendineae attachment and annuloplasty. (C) Open heart surgical view of the extravascular implantable cardioverter-defibrillator lead firmly sutured on the anterior-surface of the right ventricle. (D and E) The extravascular implantable cardioverter-defibrillator coil tunneled subcutaneously connected to the generator after sternotomy closure.

sheath was used to release the adhesions progressively up to the right atrium. Unable to proceed further with the TLE (Video 8), extracorporeal membrane oxygenation (ECMO) was initiated to remove the remaining leads through an open heart approach. Leads were cut at the atriocaval junction and then removed, with the remaining portion extracted from the subcutaneous pocket. After right atriotomy, large endocarditic masses surrounding all leads were evident (**Figure 2A**).

Proceeding to the tricuspid valve, it exhibited a significantly dilated annulus with a retracted posterior leaflet lacking chordae tendineae, along with prolapse of the commissure between the septal and anterior leaflets (**Figure 2B**). To address these issues, the posterior leaflet was folded to create a bicuspid valve, the anterior septal commissure was closed, and new chordae tendineae were attached to the anterior leaflet. Subsequently, a 28-mm MC3 prosthetic ring (Edwards Lifesciences) was implanted (**Figure 2B**, Supplemental Figure 1). Following this, right atrial suturing was performed, and the superior and inferior vena cava were freed, with temporary electrodes placed on the right ventricle. Weaning from ECMO was then successfully achieved. After replacing the venous ECMO cannula with a 27-F introducer sheath, a Micra-AV leadless PM (Medtronic) was percutaneously positioned through the right femoral vein, and it smoothly traversed the tricuspid valve (Video 9). Careful placement in the high septal region was achieved, with electrical parameter verification revealing optimal values (sensing, 6 mV; RV threshold, 0.4 V @ 0.24 ms). Following a successful traction test to confirm stability, the device was released without complications (Video 10). Electrical parameter verification demonstrated an increase in RV sensing.

Finally, after identifying the optimal location for the Aurora EV-ICD (Medtronic) generator by using fluoroscopy, a subcutaneous pocket was meticulously created in the posterior axillary region. The EV-ICD a coil was directly placed and sutured on the RV anterior surface with a polypropylene nonabsorbable, easily removable, 5-0 suture (**Figures 2C and 3A**, Video 11, Supplemental Figures 2 to 4), then tunneled subcutaneously below the xiphoid process (**Figure 2D**), and connected to the generator

FIGURE 3 Postoperative Imaging Findings



(A) Intraoperative anteroposterior fluoroscopy with complete extraction of all cardiac resynchronization therapy defibrillator leads, the leadless PM, and the extravascular implantable cardioverter-defibrillator lead on the right ventricular anterior surface before connection to the generator. (B) Final 2-projection chest radiograph highlighting the appropriate positioning of the leadless PM and the correct extravascular implantable cardioverter-defibrillator connection without pneumothorax, pleural effusion, and/or pericardial effusion, with resolving left lower lobe pneumonia.

(Figure 2E). Final checks on device parameters confirmed optimal values, showcasing a sensing signal of 4.3 mV, without any signs of atrial noise or oversensing (Figure 4A).

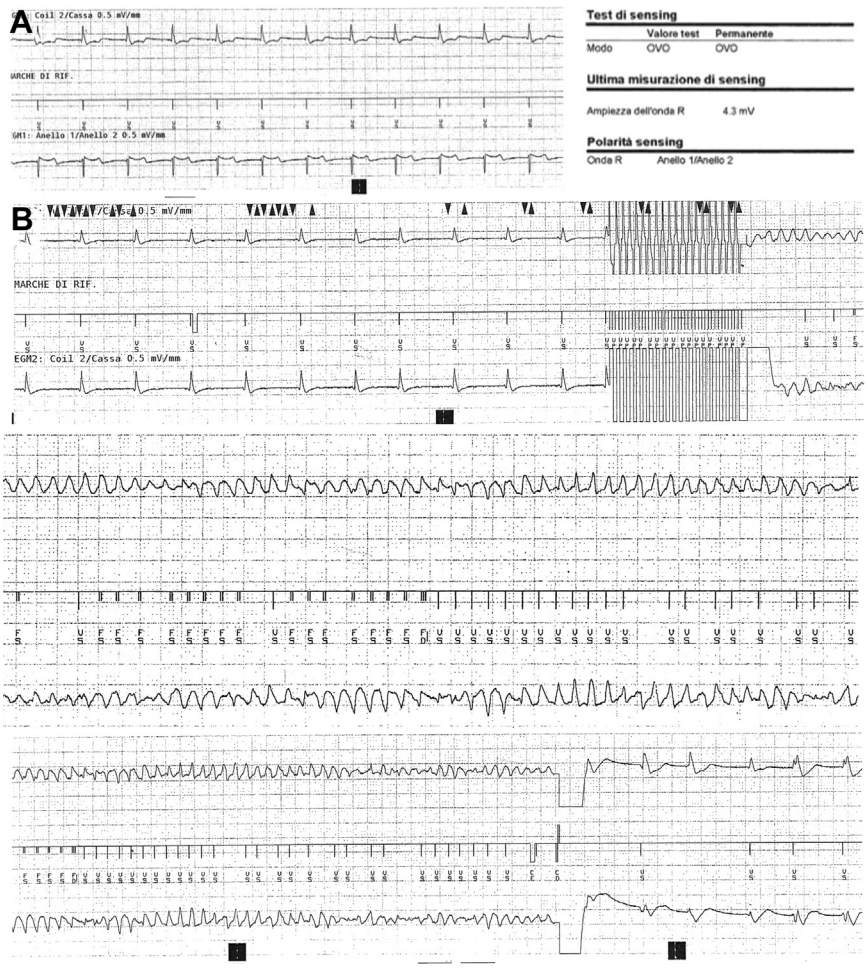
The patient was transferred to our intensive care unit. Correct functioning of both the leadless PM and the EV-ICD device was confirmed during an induction test and device parameters check (Figure 4B). Postoperative radiographic control showed correct positioning of the devices with resolving pneumonia (Figure 3B). Daptomycin and ceftaroline antibiotic therapy continued; antibiotic therapy was later transitioned to trimethoprim-sulfamethoxazole and was eventually discontinued only 2 weeks after discharge.

DISCUSSION

To our knowledge, this is the first worldwide case of a hybrid surgical and percutaneous transvenous lead extraction, coupled with concomitant tricuspid valve repair, percutaneous leadless AV-PM implantation, and—above all—EV-ICD placement with the lead sutured on the heart wall during an endocarditis process. Given the imperative for permanent pacing (absence of intrinsic cardiac rhythm), a leadless AV-PM emerged as the optimal solution in this context. Considering contraindications for transvenous lead reimplantation and the feasibility of simultaneous leadless PM insertion post-TLE,[2] this was deemed the most suitable choice. Nonetheless, the necessity for secondary protection against VAs persisted. S-ICD implantation was unfeasible because of previous unsuccessful screening, a challenge heightened in patients with congenital heart disease (up to 17%).[3] Given the lack of therapeutic alternatives available, we decided to proceed with this first-in-human open surgical approach, by suturing the EV-ICD lead to the RV anterior wall. No sensing issues possibly related to VA undersensing emerged with this approach. Although we were potentially concerned by the potential lack of stability of the EV-ICD lead, suturing the lead with 2 nonabsorbable knots at a proximal and distal level was sufficient to achieve steadiness, without fluctuation of sensing values. A possible alternative strategy to tackle this challenging case could have involved implanting epicardial leads. To our knowledge, the Aurora EV-ICD lead must sense either spontaneous ventricular activity or endocardial stimulation. Therefore, pacing with epicardial leads would have posed significant concerns regarding sensing issues, potentially resulting from the proximity of the ICD lead. Consequently, we considered that implanting an epicardial lead was not a viable option because we could not predict how the EV-ICD sensing would have behaved in this case. Additionally, a potentially quicker depletion of the pacemaker pulse-generator battery (higher pacing thresholds associated with epicardial leads) was also carefully considered in determining the final management strategy outlined in this case.

Although we remain hopeful that we will not encounter this issue in the future, if it does arise, we

FIGURE 4 **Extravascular Implantable Cardioverter-Defibrillator Sensing Parameters**



(A) Intraoperative sensing showing an R-wave amplitude of 4.3 mV. (B) Defibrillation testing performed the day after the procedure in the intensive care unit and showing ventricular fibrillation induction and appropriate device intervention; shock: 30.8 J and 34 ohm.

believe that extraction tools would be required to extract the EV-ICD lead successfully. This confidence is supported by the findings of Thompson et al[4] who demonstrated in sheep models that EV-ICD leads could not be extracted with traction alone, even when the leads were implanted in a conventional manner. Finally, we believe that a surgically placed EV-ICD should be considered only in selected cases as a bailout strategy, although our case may have paved the way for future perspectives in extremely selected patients (eg, failed S-ICD screening and no other therapeutic alternatives) requiring ICD implantation during a concomitant surgical procedure. Nevertheless, more data are needed regarding the feasibility of this technique in other cases, as well as long-term data on lead performance, to consider this procedure a "standard alternative" to traditional implantation.

FOLLOW-UP

On discharge, the patient had an LVEF of 61%. As of our most recent follow-up, which spans a duration of 3 months, the patient remained asymptomatic, with satisfactory hemodynamic stability. The parameters of the implanted device were optimal and have remained consistent with those observed at discharge. Furthermore, there has been no significant change in LVEF, a finding indicating stability in cardiac function, despite potential drawbacks associated with RV pacing alone.

CONCLUSIONS

This first-in-human case demonstrates EV-ICD lead placement feasibility during open heart surgery, thereby opening new perspectives in sudden cardiac death prevention for selected patients.

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KEY WORDS cardiac pacemaker, cardiovascular disease, endocarditis, secondary prevention, treatment, ventricular fibrillation, ventricular tachycardia

APPENDIX For supplemental figures and videos, please see the online version of this paper.