Epicardial Access: Physician Case Study with EV-ICD™ System and EPi-Ease™ Device

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Extravascular implantation of a defibrillator system is a viable alternative to transvenous implantation and mitigates the risk of endovascular infections, tricuspid valve impairment, and mechanical tension leading to lead fracture. An extravascular defibrillation system is recommended in some patients at high risk of transvenous system infection requiring a stand-alone implantable defibrillator system without brady- or resynchronization pacing needs.

Appropriate sensing of intracardiac signals represents the biggest challenge in extravascular defibrillation systems. The risk of inappropriate shocks and failure to sense ventricular defibrillation are significant clinical events that are impacted by the accuracy of sensing from defibrillator systems.

The EV-ICD system (Medtronic) is an extravascular defibrillator system with a defibrillator lead implanted in a retrosternal fashion to abut the anterior wall of the right ventricle. This position, as compared to a suprasternal position, is thought to improve sensing assuming direct contact with the pericardium. The lead is then tunneled across the chest to connect to a generator placed in the left lateral position to provide an adequate defibrillation vector.

The EV-ICD implant is performed with complimentary fluoroscopic views (anterior-posterior and left-lateral projections) to guide the position over the heart relative to the midline structures of the thorax and position in the retrosternal space. Specific to the EV-ICD system is the problem of right atrial oversensing when placing the lead directly over the anterior heart. Direct visualization of the retrosternal space, its fat content, and the distance between the sternum and pericardium would be ideal to potentially mitigate sensing issues at acute and long-term implantation of the lead.

The EPi-Ease device (AtriCure, Inc.) provides direct visualization of the retrosternal space and the pericardial sac of the heart prior to pericardial puncture for epicardial mapping and ablation. Conceivably, this tool may be useful for direct visualization of the implant space for an EV-ICD and may reduce sensing issues. Additionally, this tool may provide a mechanical tract for ease of placement of the introducer sheath and defibrillation lead.

Herein, we describe a technique used for implantation of an EV-ICD system facilitated by the EPi-Ease device utilizing a guidewire and sheath technique.

Procedure Details

A 66-year-old male with heart failure and ischemic cardiomyopathy (left ventricular ejection fraction LVEF 20%) had recently undergone a single chamber ICD system extraction and tricuspid valve vegetation removal due to persistent MRSA bacteremia. Initial ICD implant indication was for secondary prevention of sudden cardiac death. He was referred for EV-ICD system implantation given the high risk of infection and lack of pacing needs.

A pre-procedure CT scan of the heart showed normal thoracic anatomy. He was brought to the EP lab under general anesthesia for implantation of the EV-ICD system. Standard subxiphoid incision was made and dissection was made to the level of the post-anterior rectus facia. Thereafter the EPi-Ease device was prepped with a coronary guidewire and the entire system was advanced under the xiphoid into the retrosternal space under direct video visualization from the EPi-Ease thorascope and biplane fluoroscopy **(Figure 1)**.

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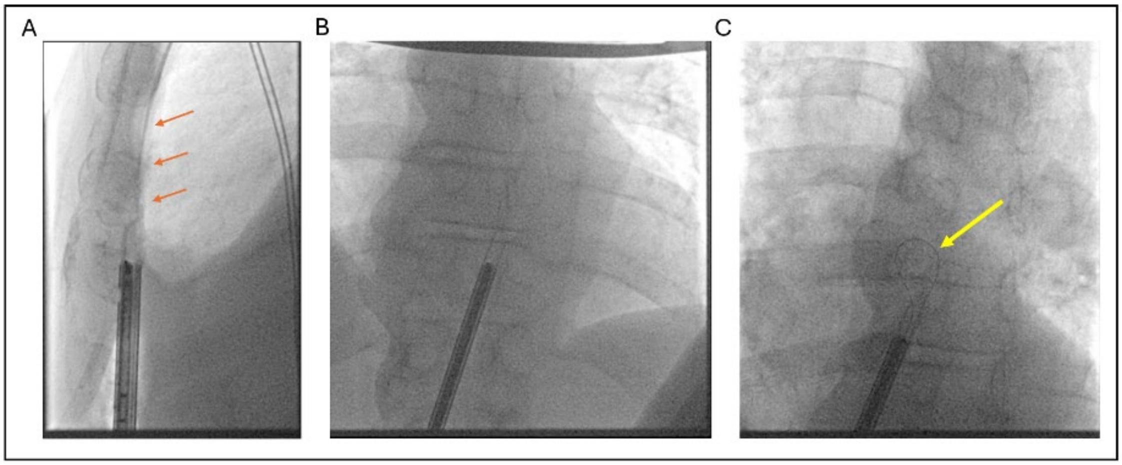
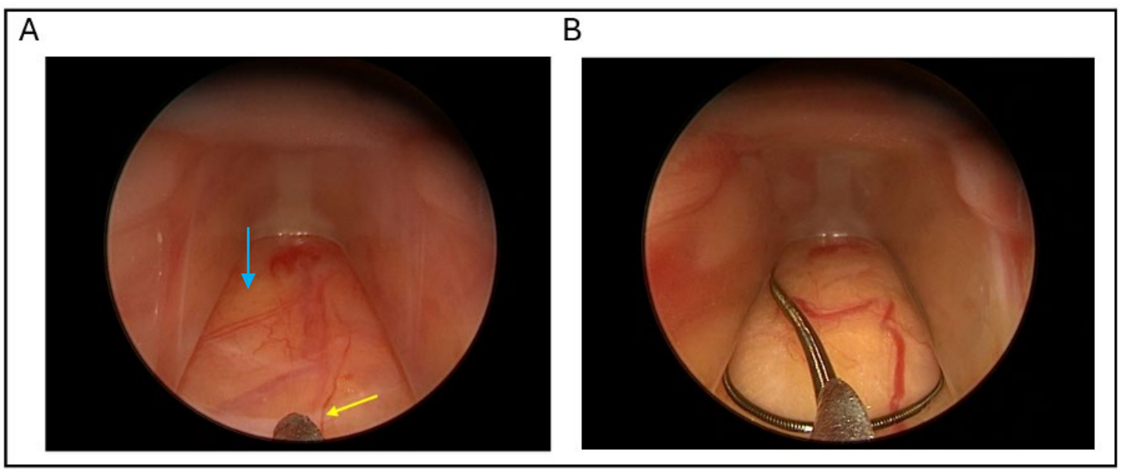
Figure 1.
Initial fluoroscopic views.



A: Left lateral view of the retrosternal space (orange arrows) and EPi-Ease device inserted under the xiphoid. **B:** Anterior-posterior view of the EPi-Ease device directly slightly oblique of midline. **C:** Coronary wire loop advanced into the retrosternal space (yellow arrow).

While advancing into position, direct visualization with the EPi-Ease device allowed us to understand the anatomy of the extra-pericardial space, direct our attention away from areas of high fat content, and produce a tract that would be ideal for placement of the defibrillation lead onto the extra-pericardial space **(Figure 2)**.

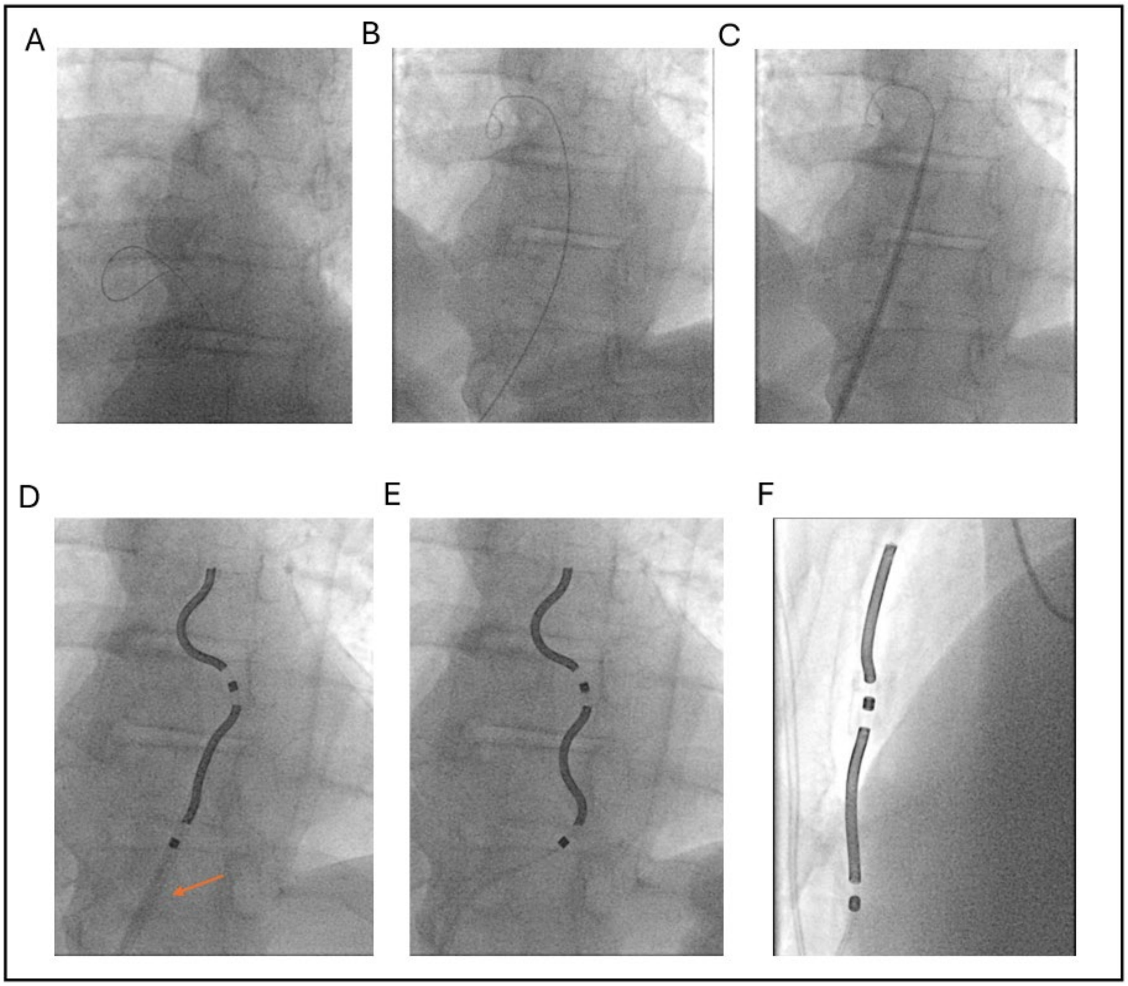
Figure 2.
Thorascopic views from the EPi-Ease device.



A: Initial view of the anterior pre-pericardial space. Note pericardial vessels (blue arrow), microbore needle (yellow arrow), and absence of fat.
B: Advancement of the coronary guidewire into the pre-pericardial space.

Once the device was positioned at the level of the left mainstem bronchus on fluoroscopy, the coronary guidewire was advanced into the retrosternal space along the track that was made. A micro-puncture introducer was advanced over this wire to exchange for a standard J-tip guidewire. A 10-french peel-away introducer was then advanced over the J-wire. The wire and dilator were removed, and a small amount of saline was instilled into the sheath to prevent and evacuate air. An EV-ICD defibrillator lead was then advanced into the sheath into the retrosternal space and the sheath was peeled **(Figure 3)**.

Figure 3.
Deployment of the defibrillator lead into the retrosternal space.



A: Coronary guidewire in the retrosternal space. **B:** J-wire in the retrosternal space. **C:** Advancement of 10-F dilator and sheath. **D:** Deployment of the defibrillator lead with retraction of the sheath (arrow). **E:** Final anterior-posterior fluoroscopic view of the defibrillator lead. **F:** Final left lateral fluoroscopic view of the defibrillator lead.

The lead was tunneled across the chest and connected to the generator in the left lateral position. Initial electrical parameters and sensing polarities are shown in **Table 1**. There was no evidence of atrial oversensing, and an above-average initial R-wave was obtained in multiple configurations.

Table 1. Acute implant electrical characteristics.

Sensing polarity	R-Wave (mV)	Pacing Impedance (Ohms)	HV Impedance (Ohms)
R1-R2	3.7	437	64
R2-Can	6.5		
R1-Can	3.6		

R1 = ring 1; R2 = ring 2; HV = high voltage.

Defibrillation testing was then performed two times with successful detection and defibrillation of ventricular fibrillation with 31 joules on each occasion.

The patient was monitoring overnight without any complications. The following post-operative day, the electrical parameters of the EV-ICD were assessed and are displayed in **Table 2**. Sensing was accurate with a diminutive P-wave and absence of atrial oversensing in all sensing configurations.

Table 2. Electrical characteristics at post-operative day one.

Sensing polarity	R-Wave (mV)	Pacing Impedance (Ohms)	HV Impedance (Ohms)
R1-R2	4.5	230	44
R2-Can	4.5		
R1-Can	5.0		

Abbreviations as per Table 1.

The patient was discharged home on post-operative day one without complications. At 1-month follow-up, electrical parameters were stable without P wave oversensing (Table 3).

Table 3. Electrical parameters at 1-month follow-up.

Sensing polarity	R-Wave (mV)	Pacing Impedance (Ohms)	HV Impedance (Ohms)
R1-R2	2.7	247	54

Conclusions

Extravascular ICDs represent a novel solution to transvenous lead related complications. Appropriate positioning of the defibrillator lead in the retrosternal space may require multiple attempts to achieve an adequate R-wave and avoid atrial oversensing in the EV-ICD system.

The EPi-Ease device provided direct visualization of the retrosternal space and the underlying pericardium and helped determine the best position of the lead overlying the pericardium. The wiring and sheath technique used in this case helped to mitigate migration of the lead into a different position after tract formation. The electrical parameters at implant and follow-up were excellent.

Note: *This whitepaper was supported by AtriCure. Results from case studies are not necessarily predictive of results in other cases. Please exercise your own independent medical judgement.*

U.S. Indications: *The EPi-Ease Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.*

Rx Only.

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