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ELECTROPHYSIOLOGY

Three-year extraction experience of a novel substernal extravascular defibrillation lead in sheep

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Abstract

Background: The extravascular implantable cardioverter-defibrillator (EV ICD) with lead implantation in the substernal space may provide an alternative to transvenous and subcutaneous systems. This is the first-reported chronic extraction experience for EV ICD leads. The aim of the study is to evaluate the chronic encapsulation and extractability of EV ICD leads.

Methods: Two EV ICD leads and one transvenous lead were implanted in each of 24 mature sheep. A subset of animals was evaluated yearly for histology and lead extractability. Extractions were performed using simple traction or extraction tools. Histology evaluated the encapsulating tissue.

Results: At 1 year, extraction was performed successfully for two of five EV ICD leads with traction alone using ≤3.1 kg-force (kgf) and the remainder extracted successfully with extraction tools; no transvenous leads were removed with traction alone. At 2 years, no EV ICD or transvenous leads were extracted with traction alone, while at 3 years, one of eight EV ICD leads and two of four transvenous leads were extracted with traction (0.8 and ≤2.3 kgf, respectively). There was one observation of hemopericardium resulting in tamponade with EV ICD extraction but without injury to cardiovascular structures and related to the unique implant tract. Among transvenous leads, inversion of the ventricle with loss of cardiac output resulted in abandonment of traction for two animals.

Conclusions: Chronic extraction of EV ICD leads from the substernal space was successfully performed using traction and simple tools through 3 years in sheep with one observation of hemopericardium that did not originate from cardiovascular injury.

KEYWORDS
encapsulation, extraction, extravascular, substernal

Abbreviations: TV-ICD, transvenous implantable cardioverter-defibrillator; SQ-ICD, subcutaneous ICD; ATP, antitachycardia pacing; EV ICD, extravascular implantable cardioverter-defibrillator; ITA, internal thoracic artery

1 | INTRODUCTION

The transvenous implantable cardioverter-defibrillator (TV-ICD) has served for decades as the device-based standard of care to protect patients from sudden cardiac death, yet post-implant issues such as lead fracture, venous obstruction, and infection have persisted, often necessitating system removal or extraction.[1,2] Although high-volume centers observe higher success and lower complication/mortality rates with transvenous lead extraction than low-volume centers,[3,4] serious complications requiring surgical or endovascular intervention remain, including vessel laceration and cardiac perforation.[5] Further, post-procedural and long-term mortality associated with transvenous lead extraction remain high in certain populations, including elderly patients or those undergoing extraction for infectious indications.[4]

The subcutaneous ICD (SQ-ICD) has emerged as an alternative to TV-ICD, avoiding lead implantation in the heart or vasculature.[6] Recently reported experience with the SQ-ICD demonstrated the ability to remove or extract the subcutaneous lead in 96.9% of patients after a median implantation duration of 9.3 months.[7] However, the SQ-ICD is not without limitations; it cannot deliver antitachycardia pacing (ATP) and uses high energy for defibrillation, requiring a device that is larger and has reduced longevity compared with transvenous systems.[8,9]

The extravascular implantable cardioverter-defibrillator (EV ICD) with lead placement in the anterior mediastinum (substernal space) (Figure 1) may prove to be a valuable alternative to TV- and SQ-ICDs.[10–13] Recent first-in-human experience with the EV ICD has demonstrated the feasibility of implanting within the substernal space and successfully pacing and defibrillating using a device size equivalent to modern transvenous defibrillators.[13] Although early lead removals at 85 and 114 days were successful without complication in the first-in-human experience,[13] chronic extractability from the substernal space is unknown at present. We present the 3-year extraction experience of the substernal EV ICD lead in sheep.

2 | METHODS

2.1 | Study design

A total of 24 mature sheep (Hampshire Down) were implanted with EV ICD leads in the substernal space to assess lead extractability and tissue encapsulation properties, 15 of which were used for evaluation through 3 years and the remainder retained for extraction evaluation at years 4 and 5. Each animal was implanted with two EV ICD leads—one toward the left and one toward the right sternal border within the substernal tissues—as well as one transvenous endocardial control lead in the right ventricle (RV). The study conformed with the Guide for the Care and Use of Laboratory Animals and was approved by the Institutional Animal Care and Use Committee.

EV ICD leads were implanted via a subxiphoid incision and the use of a malleable stainless steel tunneling rod backloaded with a 9-French introducer sheath, through which the lead was positioned over the RV cardiac silhouette. Each EV ICD lead was sutured via an anchoring sleeve at the xiphoid incision site. The implanted EV ICD lead proximal ends were placed in subcutaneous pockets on respective sides of the sheep without connection to an ICD to limit forces acting on the lead that might disturb tissue capsule formation. The transvenous lead was implanted via jugular access.

At each year post-implant until study conclusion at 5 years, a subset of sheep has undergone or will undergo lead extraction according to a pre-determined extraction protocol; experience to date is limited to 3 years. In addition, a subset of leads was preserved in situ to allow for histopathology assessment of the undisturbed perilead tissue capsule

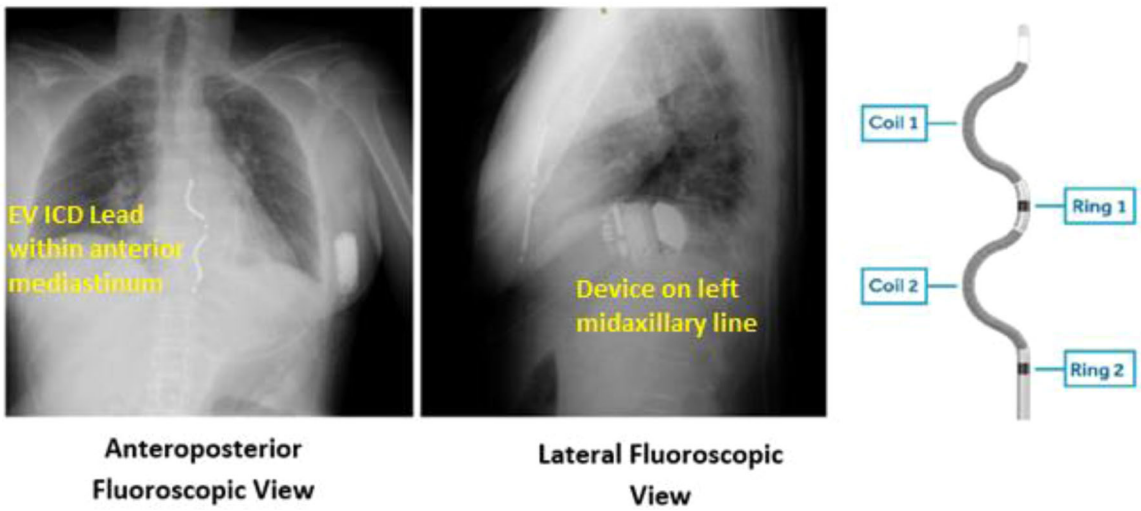

FIGURE 1 Extravascular implantable cardioverter-defibrillator (EV ICD) implant and lead. Fluoroscopy images of the EV ICD system in a human (left image); EV ICD distal lead construction (right image) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Summary of subjects for extraction or histology

Years post-implant	Subject ID #	Left substernal lead	Right substernal lead	Transvenous lead
<1[a]	305	Preserved in situ	Preserved in situ	Not preserved
1	314	Extracted	Extracted	Extracted
1	315	Preserved in situ	Preserved in situ	Extracted post-mortem at necropsy[b]
1	316	Extracted	Extracted	Extracted
1	323	Preserved in situ	Extracted	Extracted
2	313	Preserved in situ	Preserved in situ	Preserved in situ
2	318	Extracted	Extracted	Extracted
2	319	Preserved in situ	Preserved in situ	Preserved in situ
2	320	Extracted	Extracted	Extracted
2	322	Preserved in situ	Preserved in situ	Preserved in situ
2	324	Extracted	Extracted	Extracted
3	302	Extracted	Extracted	Extracted
3	303	Extracted	Extracted	Extracted
3	309	Extracted	Extracted	Extracted
3	311	Extracted	Extracted	Extracted

[a]This animal died at 127 days.
[b]Pull force data were not collected because extraction was conducted outside the operating theater.

(Table 1); in situ histopathology analysis was limited to the first 2 years of study, when the fibrotic capsules showed complete maturity. In animals undergoing extraction procedures, necropsy and pathology evaluations were also completed through the first 2 years, but the perilead tissue capsule was not evaluated histologically due to capsule disruption during extraction.

2.2 | Lead designs

The EV ICD lead is an 8.7-French dual-coil epsilon-shaped lead composed of polyurethane (Figure 1) that is not commercially available. There are two coil electrodes for defibrillation and two ring electrodes for pacing and sensing. Each defibrillation coil is 4 cm in length, and for defibrillation purposes, the coils are coupled.

The transvenous lead (Model 6947 Sprint Quattro Secure MRI SureScan, Medtronic) is an 8.6-French dual-coil, quadripolar, active fixation lead with polyurethane overlay intended for implantation within the RV.

2.3 | Extraction protocol

Prior to extraction, the leads were prepared according to the following sequence:

1. The lateral subcutaneous pocket containing the EV ICD lead proximal end was incised and freed from fibrotic tissue
2. The proximal lead body was retracted from the lateral pocket to the xiphoid incision
3. The anchoring sutures were cut and the anchoring sleeve removed
4. The lead body was prepared by cutting and stripping the insulation; the conductor cables were captured using a Bulldog lead extender (Cook Medical) or tied together and secured with a silk suture to the lead body and cables
5. A force gauge was attached to the sutures/cables and connected to a recording system

The transvenous lead was prepared via a similar procedure, except that a jugular pocket was excised to free the lead body from fibrotic tissue (step 1) and the conductor cables were tied together and a locking stylet inserted into the inner lumen of the lead (step 3).

After preparing the lead for extraction, either traction or extraction tools could be used. Investigator discretion ultimately determined whether traction alone or mechanical tools should be used to complete the extraction process; in general, the lead was gently tugged to help evaluate whether adhesions were present, and when fibrotic adhesions allowed the lead to act as a rail for the extraction tool to track over, extraction tools were typically used instead of traction to remove the leads. Extraction tools included telescoping dilator sheaths of polypropylene or stainless steel (LR-TELSST002, Byrd) or a proprietary mechanical extraction sheath with novel powered tissue dissection feature (Medtronic). If traction was used, it was applied in incremental steps, beginning with 1 kg-force (kgf) and increasing to 2 and 3 kgf for 2 min each until the lead released from encapsulating tissue or investigator discretion determined that traction should be abandoned.

FIGURE 2 Extravascular implantable cardioverter-defibrillator (EV ICD) tissue capsule. Extracted EV ICD lead (2 years) showing representative tissue capsule [Color figure can be viewed at wileyonlinelibrary.com]

2.4 | Monitoring

Animals remained anesthetized and were assessed for any potential extraction-related complications for 1 h following extraction.

2.5 | Pathology/histology

Post-mortem examination included necropsy for all animals and subsequent histopathology characterization of leads that were preserved in situ, including measurement of capsular thickness, maturity, and inflammation. Tissues were fixed post-mortem in 10% formalin and trimmed for histology processing via standard methods. Capsule maturity and inflammation were scored from 0–2 or 0–4, respectively, with lower scores indicating more advanced healing.

3 | RESULTS

Through 3 years, 15 female sheep (56 ± 17 kg, average ± standard deviation) were evaluated for extraction or encapsulation profile (Figure 2). Among these, 14 were euthanized per standard protocols and one died at 127 days of causes not apparently related to the implanted EV ICD devices (#305). Across 3 years, 19 EV ICD leads were extracted and 11 were preserved in situ for histology, including both leads of the sheep (#305) who died at 127 days. Comparatively, 10 transvenous leads were extracted per the defined extraction protocol prior to termination, one was extracted post-mortem, and three were preserved in situ for histology.

3.1 | One-year extractions

At 1 year, EV ICD lead extraction was successfully performed for all five leads from three sheep without complications (Table 2). Three EV ICD leads underwent the traction protocol, and two released from encapsulating tissues at 2.8 and 3.1 kgf. Traction was abandoned at 4.1 kgf for the third lead and a telescoping sheath used thereafter to successfully extract the lead. Two additional leads were extracted using extraction tools without use of direct traction first, both of which were easily dissected from the scar tissue. Minor histopathology observations were focal reddening of the pericardial sac in one animal (#316, left lead) and a small point of insignificant focal bleeding in the sternal musculature in two animals (#314 right lead and #323 right lead), all without sequelae.

By comparison, no transvenous leads were removed with traction alone at 1 year. Two transvenous leads underwent traction prior to the use of extraction tools (to 1.1 and 3.0 kgf), but neither released from the encapsulating tissues. The third lead underwent the extraction procedure using extraction tools without traction applied beforehand. All three leads were extracted in their entirety without complications. One additional transvenous lead (#315) was extracted post-mortem at necropsy without traction measurements. One small focus of acute myocardial injury due to lead extraction was noted in this animal, presumed to be inconsequential for heart function. Additional minor histopathology observations included pinpoint reddening in the trabeculae and inconsequential acute hemorrhage at the RV implant site without sequelae.

3.2 | Two-year extractions

At 2 years, no EV ICD leads were extracted with traction alone. Traction was applied in three animals without effect (to 3.3, 3.4, and 4.1 kgf) before using extraction tools. Three additional EV ICD leads were extracted using extraction tools without application of traction first. In one subject (#318), hemopericardium resulting in tamponade was observed, but without damage to the heart or cardiac vessels. Pathology revealed that the course of the EV ICD lead implant had incorporated the pericardial sac, entering into and then out of the pericardium, with the lead tip then becoming lodged in the ventral chest wall. At extraction, disruption of the lead tip in the chest wall resulted in bleeding from the internal thoracic artery (ITA). Because of the fibrotic tissue conduit that had formed along the lead path, blood flowed backward through the conduit from the chest wall into the pericardium, resulting in hemopericardium and tamponade. There was no cardiac or vascular injury from within the pericardium itself. There were no other complications observed among EV ICD leads extracted at 2 years. One minor histology observation was disruption of the pleura in one animal (#324) without sequelae.

Similarly, no transvenous leads were extracted with traction alone at 2 years. In one animal, the transvenous lead was extracted using extraction tools without application of traction first. In the remaining two animals, traction was applied (to 1.4 or 2.4 kgf) and the RV inverted and cardiac output was lost; traction was abandoned in favor of extraction tools in both cases, and both leads were extracted successfully. In both animals, histopathology showed endocardial/myocardial tearing; in one, tearing of the endocardium resulted in focal acute hemorrhage and thrombus formation, while in the other, endocardial and

TABLE 2 Summary of EV ICD and transvenous lead extraction results

Years post-implant	Subject ID #	Summary	Left substernal lead	Right substernal lead	Transvenous lead
1	314	Traction	No traction applied	Lead extracted with traction (3.1 kgf)	No traction applied
		Tools	Proprietary tool	n/a	Proprietary tool and telescoping sheaths
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications
1	316	Traction	No traction applied	Lead extracted with traction (2.8 kgf)	Traction applied to 1.1 kgf without effect
		Tools	Proprietary tool	n/a	Proprietary tool and telescoping sheaths
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications
1	323	Traction	n/a (lead preserved in situ)	Traction applied to 4.1 kgf without effect	Traction applied to 3.0 kgf without effect
		Tools		Telescoping sheaths	Proprietary tool and telescoping sheaths
		Outcome		Lead extracted without complications	Lead extracted without complications
2	318	Traction	No traction applied	Traction applied to 4.1 kgf without effect	No traction applied
		Tools	Proprietary tool	Telescoping sheaths	Proprietary tool
		Outcome	Hemopericardium with tamponade but without injury to heart/vasculature		Lead extracted without complications
2	320	Traction	No traction applied	Traction applied to 3.3 kgf without effect	Traction applied to 1.4 kgf and abandoned when RV inverted and no cardiac output observed
		Tools	Proprietary tool	Proprietary tool	Proprietary tool
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted with endocardial tearing and focal acute hemorrhage and thrombus
2	324	Traction	No traction applied	Traction applied to 3.4 kgf without effect	Traction applied to 2.4 kgf and abandoned when RV inverted and no cardiac output observed
		Tools	Proprietary tool	Proprietary tool	Proprietary tool
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted with endocardial/myocardial injury and focal moderate myocardial hemorrhage and thrombus deposition onto injured endocardial surface
3	302	Traction	No traction applied	Lead extracted with traction (0.8 kgf)	No traction applied
		Tools	Proprietary tool	n/a	Proprietary tool
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications
3	303	Traction	No traction applied	Traction applied to 3.2 kgf without effect	Lead extracted with traction (2.3 kgf)

(Continues)

TABLE 2 (Continued)

Years post-implant	Subject ID #	Summary	Left substernal lead	Right substernal lead	Transvenous lead
		Tools	Proprietary tool	Proprietary tool	n/a
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications
3	309	Traction	No traction applied	No traction applied	Lead extracted with traction (2.1 kgf)
		Tools	Proprietary tool and telescoping sheaths[a]	Proprietary tool	n/a
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications
3	311	Traction	Traction applied to 3.0 kgf without effect	No traction applied	No traction applied
		Tools	Proprietary tool	Proprietary tool	Proprietary tool
		Outcome	Lead extracted without complications	Lead extracted without complications	Lead extracted without complications

EV ICD, extravascular implantable cardioverter-defibrillator; n/a, not available.
[a]It is suspected that the anchoring sleeve remained in place during extraction of this lead.

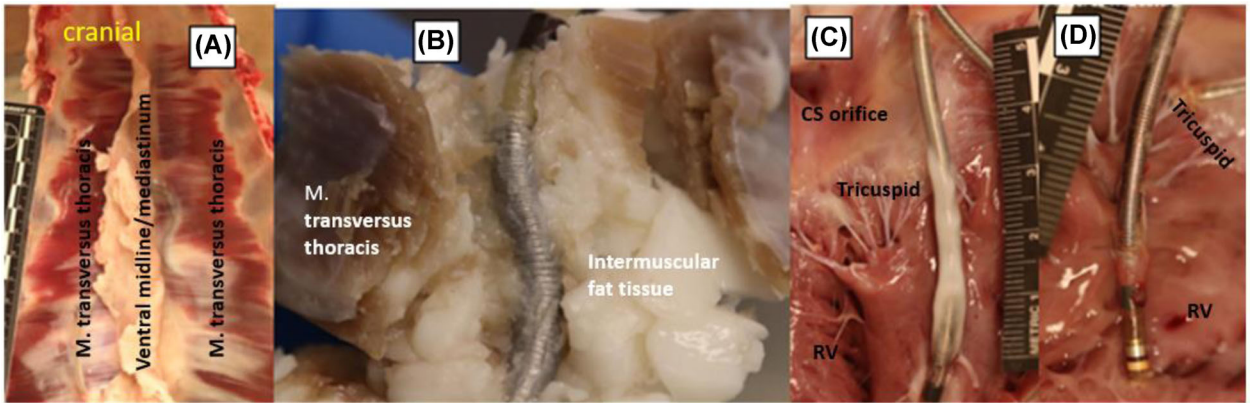

FIGURE 3 Pathology examination. EV ICD implant location in the substernal anatomy (A) with fixed tissue capsule (B); transvenous lead in the RV implant location (C, D). EV ICD, extravascular implantable cardioverter-defibrillator; RV, right ventricle [Color figure can be viewed at wileyonlinelibrary.com]

myocardial injury resulted in focal moderate myocardial hemorrhage and thrombus deposition onto the injured endocardial surface.

3.3 | Three-year extractions

At 3 years, one EV ICD lead was extracted with traction alone (0.8 kgf). Traction was applied to two additional EV ICD leads (to 3.0 and 3.2 kgf) without effect before abandoning traction and using extraction tools, with both leads extracted successfully. Five additional EV ICD leads were extracted using extraction tools without traction applied first. There were no complications of EV ICD lead extraction at 3 years.

Comparatively, two of four transvenous leads were extracted with traction alone (at 2.1 and 2.3 kgf) without complications, while two additional transvenous leads were extracted using extraction tools without traction applied first.

3.4 | Histopathology of in situ leads

The pathology findings reflected the extraction results (Figure 3). Among EV ICD leads retained in situ for histopathology, tissue capsules were of variable thickness within and between animals, and an absence of tissue capsule was more commonly noted at earlier time points (Figure 4). Among animals implanted for 1 year, capsule thickness measures at electrode regions ranged from − 52 to 442 μm compared to a range from 83 to 1414 μm observed at 2 years. The largest capsule thicknesses overall were observed at the S2 proximal ring electrode nearest the xiphoid incision, most particularly at 2 years. At both the 1- and 2-year time points, mature tissue capsules with low cellularity and inflammation were observed at the EV ICD electrode sites (Figure 5). EV ICD capsule maturity scores ranged from 0 to 1 and showed no marked differences between time points or electrode

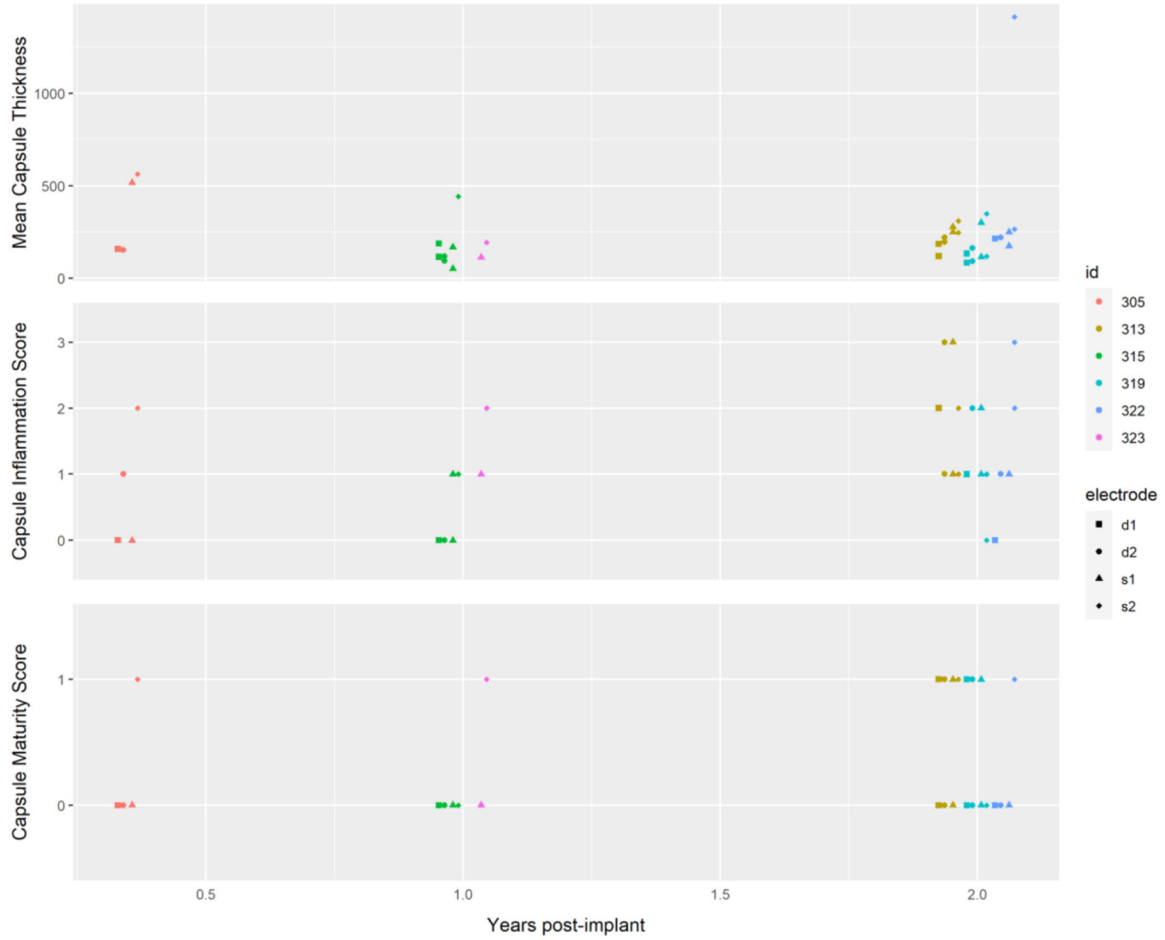

FIGURE 4 Histology summary for Extravascular implantable cardioverter-defibrillator (EV ICD) leads in situ [Color figure can be viewed at wileyonlinelibrary.com]

location; similarly, median capsule inflammation scores ranged from 0 to 3 across time points and electrode locations. EV ICD electrodes were commonly implanted adjacent to adipose or connective tissue of the mediastinum and less frequently adjacent to pleura or muscle tissues.

At necropsy, four EV ICD leads were found to be implanted at least partially in the pleural cavity (#305 [side not labeled], #315 right lead, #319 right lead, #322 right lead). In addition, the left EV ICD lead of one animal (#319) was implanted predominantly in the mediastinum but the proximal lead region exited the rib cage without consequence. Tightly adhered tissue capsules were observed around the D1 and D2 EV ICD defibrillation coils of five leads, including one lead at 1 year (#323 left lead) and four leads of two animals evaluated at 2 years (#319 and #322).

By comparison, the tissue capsule of the transvenous leads ranged from 314 to 660 μm at 2 years among leads preserved in situ for histopathology. Regions free from capsule formation were more commonly noted at the proximal end of the transvenous lead coil as opposed to the distal and middle sections. Capsule maturity scores ranged from 0 to 1 and median capsule inflammation scores ranged from 0 to 2, indicative of advanced healing. A small amount of organizing thrombus was observed on the distal aspect of the transvenous lead of one animal (#313) at 2 years.

4 | DISCUSSION

Extravascular ICD system implantation represents an important alternative to the TV-ICD for patients where it is not possible or desirable to position leads within the vasculature, helping to avoid transvenous lead complications such as fracture, endovascular infection, and the attendant concerns with lead extraction.[1–5] Although the SQ-ICD has emerged as an extravascular option, it is not without limitations, such as large device size and lack of ATP and brady support pacing.[8,9] The EV ICD is being developed to overcome such limitations by providing defibrillation and pacing therapies with a smaller device.[10–13] A complete understanding of extravascular lead extraction is thus still emerging for SQ-ICD and is required for EV ICD.

Recently reported experience with the SQ-ICD demonstrated the ability to explant the subcutaneous lead in 96.9% of patients after a median implant duration of 9.3 months (range: 5.4–17.5 months); among 32 patients analyzed, simple traction was successful in 19

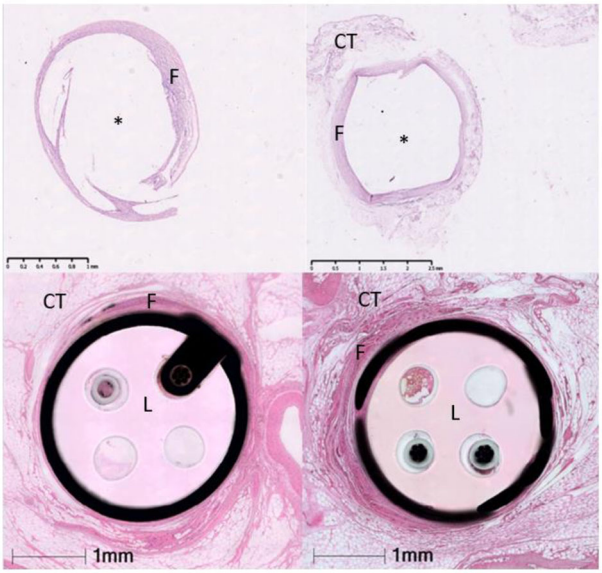

FIGURE 5 Histology examination. Representative EV ICD mature tissue capsule histology from 1 year (top panel, lead removed from tissue leaving a void (*)) showing minimal inflammation and from 2 years (bottom panel, with lead cross-section remaining in tissue) showing mild, focal inflammation. Both HE stains and scale bars inserted. Inflammation is not discernable at this magnification. CT, fatty perilead connective tissue; F, perilead fibrosis; L, lead. EV ICD, extravascular implantable cardioverter-defibrillator; HE, hematoxylin and eosin [Color figure can be viewed at wileyonlinelibrary.com]

(59.4%), a mechanical sheath was required in nine (28.1%), an additional incision was required in three (9.4%), and there was one procedure failure (3.1%).[7]

Similar results were observed in our study. At 1 year, simple traction was successful for two of five EV ICD leads (40%), and an extraction tool was required for the remaining three leads as well as for all but one EV ICD lead at later time points. Across 3 years, there were no additional incisions required for extraction, and there were no procedure failures. By contrast, extraction tools were required for all transvenous leads at 1 year and eight of 10 transvenous leads through 3 years.

Across multiple reports, the SQ-ICD defibrillation coil has been the site of adhesion formation, limiting the success of direct traction in freeing the distal portion of the SQ-ICD lead, requiring the use of additional incisions to disrupt adhesions, and necessitating the use of laser or mechanical extraction tools.[7,14,15] Patel et al. describe a 37-year-old patient who underwent SQ-ICD system extraction at 506 days. Although the proximal portion of the lead was readily freed from the tunneling path between the xiphoid incision and the device pocket, removal of the distal portion of the lead containing the SQ defibrillation coil proved challenging, requiring the use of a Bulldog lead extender, an Amplatz Goose Neck snare, and a TightRail rotating mechanical dilator sheath.[14]

In our study, tightly adhered tissue capsules were noted on the defibrillation coils of five EV ICD leads through 2 years, indicative of advanced capsule maturity. The physician performing extractions noted a preference for a 13-French extraction tool as opposed to an 11-French tool to cut away larger capsule regions, as well as to navigate EV ICD coil bends. Despite this, the greatest tissue capsule thicknesses occurred at the proximal ring electrode nearest the xiphoid incision site.

Overall, capsule thicknesses were greater for transvenous leads than EV ICD leads in our study, presumably reflecting a difference in lead implantation within the blood pool versus a substernal tissue environment. Because the limited vascularization of the substernal space could extend tissue capsule formation time course, more experience will be needed to understand EV ICD lead encapsulation at longer implant durations; 4- and 5-year extraction data from animals is forthcoming. However, the limited vascularity of the substernal space may make it an attractive target for lead extraction compared to endovascular locations.

One serious observation of hemopericardium resulting in tamponade was noted in our study; however, this occurred without injury to the heart or cardiac vasculature. Histopathology determined that the EV ICD lead had traversed the pericardium at implant, creating a conduit into the pericardium via the lead path that allowed blood from the disrupted ITA to flow intrapericardially. This observation is likely a consequence of the animal model. The sheep pericardium is markedly thinner than that of humans, increasing likelihood of penetration[16]; in addition, the ITA in humans is offset from the sternal edges by 1.47 ± 0.30 cm.[17] In our study, the EV ICD leads were intentionally positioned toward the sternal borders to accommodate two leads per animal, creating a likelihood for the lead to come in close contact with the thoracic vessels, and notably, four EV ICD leads were implanted at least partially within the pleural cavity adjacent the mediastinum.[18] Aside from the unique instance of hemopericardium without cardiovascular injury, there were no complications related to EV ICD lead extraction through 3 years.

The sheep model was chosen based on the work of Wilkoff et al., who reported extraction experience of ICD leads in sheep at 6 and 14 months as a reasonable standard of lead extractability testing; however, our evaluation extended the implant duration to 3 years to more fully characterize longer-term extractability within a novel implant space.[19]

A standard protocol for EV ICD lead extraction from humans may emerge with more clinical experience. After excising and freeing the EV ICD lead from fibrotic tissue, it would be possible to extract the lead as performed in the extraction study presented here, whereby the proximal lead body is first retracted from the lateral pocket to the xiphoid incision site and then the distal end of the lead is extracted from the substernal space; however, it is also anticipated that the EV ICD lead could alternately be extracted by removing the anchoring sutures and retracting the distal portion of the lead from the substernal space before retracting the lead back to the lateral device pocket.

Additional data from human subjects, most especially in juveniles and other unique populations, will be needed to fully assess the extractability of EV ICD leads from the substernal space.

4.1 | Study limitations

This evaluation was conducted in sheep, which may have anatomical and physiological characteristics that limit the extrapolation of results to humans. Only female sheep were used. Distal EV ICD lead segments were implanted without connection to an ICD generator, which might not adequately replicate tension forces acting on the lead and thereby the encapsulation/extraction profile.

5 | CONCLUSIONS

Mature tissue capsules with low cellularity and inflammation were observed on the EV ICD lead at 1 year and later. Chronic removal of the novel EV ICD lead from the substernal space was performed using traction and simple tools through 3 years in sheep, with one observation of hemopericardium that did not originate from cardiovascular injury. These results may indicate that removal of EV ICD leads can be performed safely up to 3 years post-implant.

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AUTHOR CONTRIBUTIONS

Amy E. Thompson and Mark Marshall were responsible for writing the study protocol and obtaining funding; Mark Marshall, Linnea Lentz, and Hector Mazzetti were responsible for the collection of data; Mark Marshall devised the pull force data collection apparatus; Linnea Lentz assisted with the implant methodology and gross pathology evaluation; Hector Mazzetti performed all extraction procedures. Amy E. Thompson was the main writer, and all authors reviewed the final manuscript. All authors contributed to data analysis and review.

CONFLICT OF INTEREST

Amy E. Thompson, Mark Marshall, and Linnea Lentz are employees of and Hector Mazzetti is a consultant for Medtronic plc.

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