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Facilitation of transvenous lead extraction using site-specific delivery of electrosurgical energy

John N. Catanzaro, Menekham Zviman, Aravindan Kolandaivelu, Saman Nazarian, Henry Halperin, Ronald D. Berger, Jeffrey A. Brinker, Alan Cheng *

Section of Cardiac Electrophysiology, Division of Cardiology, The Johns Hopkins Hospital, Baltimore, MD, United States

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ABSTRACT

Introduction: Excimer laser energy is often required to extract chronically indwelling pacemaker and defibrillator leads from the vasculature and myocardium. This technique can be associated with vascular and right ventricular (RV) injuries. We sought to develop a safer, more effective method by applying site-specific delivery of electrosurgical energy (EE).

Methods: Utilizing a polyacrylamide gel model to simulate soft tissue density, active and passive fixation defibrillator and pacemaker leads were implanted and manually extracted with and without EE delivered to the cathode. The amount of force required for complete removal was measured using a force transducer. The procedure was then repeated in an acute pig model to demonstrate proof of safety. Post mortem gross and histologic specimens were collected from the implantation site.

Results: In the gel model, the force required for extraction, using manual traction in the active (83.7 g) and passive (74.6 g) fixation ICD leads, was reduced by 37.8% and 33.5%, respectively with EE (both $p < 0.01$). The force required for extraction, using manual traction in the active (85.2 g) and passive (71.9 g) fixation pacemaker leads, was reduced by 64.4% and 42.6%, respectively with EE (both $p < 0.01$). In an acute implantation pig model using an active fixation lead, delivery of EE to the cathode ($n = 6$) reduced the force required to manually extract the lead (140 g +/− 32.5 versus 82 g +/− 14.7, $p = 0.03$). Post mortem analysis of the RV displayed formation of an epicardial hemorrhagic lesion that was also present after manual traction and EE. There was absence of pericardial effusion, perforation, and ventricular arrhythmia.

Conclusions: Site-specific delivery of EE to areas of exposed metal along the lead decreased the force necessary for lead extraction in an in vitro and in vivo model. Further studies are needed to evaluate its application in clinical care.

1. Introduction

The number of implanted cardiac implantable electronic devices (CIEDs) has steadily increased over the past decade. The emergence of pacing and implantable cardioverter–defibrillator (ICD) systems, along with expanding indications of these devices (e.g., cardiac resynchronization therapy and sudden cardiac death prevention), increasing infection rates, and device recalls has created a greater need for removing and upgrading indwelling transvenous leads [1]. Unfortunately, lead removal is often complicated by the development of a fibrous material around the leads over time. In fact, the longer the indwelling lead has been implanted, the more difficult the process of extraction. In-depth analyses of extracted leads have shown that fibrous adhesions do not occur uniformly over the length of the lead. In fact, there appears to be a greater predilection for fibrous tissue development at the defibrillator coils and the tip of the implanted lead [2–6]. Defibrillator coil-associated adhesions have often required the application of more advanced methodologies beyond simple traction such as dilating sheaths, snares, and excimer laser sheaths. But when only the tip of the lead remains fibrosed to the myocardial wall, few options are available for safe removal. The current standard of care is the application of increasing degrees of manual traction. This can either result in hemodynamically significant right ventricular eversion or potentially fatal vascular or myocardial avulsions. We sought to develop a potentially safer method of freeing the lead tip from fibrous adhesions through site-specific energy delivery capable of disintegrating fibrous tissues at regions of the lead most prone to tissue formation. We hypothesized that delivering electrosurgical energy to these sites would

Abbreviations: CEID, cardiac implantable electronic devices; ICD, implantable cardioverter defibrillator; PPM, permanent pacemaker; EE, electrosurgical energy; SVC, superior vena cava; RA, right atrium.

* Corresponding author at: 600 N. Wolfe Street, Carnegie 568, Baltimore, MD 21287, United States. Tel.: +1 443 287 2939; fax: +1 443 873 5019.
E-mail address: alcheng@jhmi.edu (A. Cheng).

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provide a safer means of facilitating chronically indwelling lead removal.

2. Methods

Utilizing a 4.0% polyacrylamide gel model to simulate fibrous tissue density, active and passive fixation defibrillator (Medtronic Sprint Quattro 6947, Mounds View, MN) and pacemaker leads (St Jude Tendril 1888, Sylmar, CA) were implanted and manually extracted with and without EE delivered to the cathode in a unipolar configuration. The amount of force required for complete removal was measured using a force transducer for a total of eighty lead extraction removal procedures. The procedure was then repeated in an acute pig model to demonstrate proof of safety. The porcine internal jugular vein was located via ultrasound and vascular sheaths were inserted via a modified Seldinger technique. The transvenous pacemaker lead was then inserted through the sheath into the right ventricle under fluoroscopic guidance. A secure site was found and in the case of an active fixation lead, the helix was deployed. A force transducer was attached to the proximal portion of the lead. The lead was then extracted using manual traction and the force required to extract the lead from the myocardium was measured. The same procedure was then repeated with EE. An alligator clip was attached to the portion of the lead pin that corresponded to the cathode of the lead. Unipolar EE was delivered utilizing a standard electrosurgical device (Covidien, Mansfield, MA) programmed to a maximum output with a 100% duty cycle. During EE delivery manual traction was applied and the force required to extract the lead from the myocardium was recorded. In both groups a live fluoroscopic image was taken and stored to demonstrate the course of the lead during extraction. This process was repeated with the defibrillator lead. Both active and passive fixation mechanisms were used. Post mortem gross and histologic specimens were then collected from the implantation site.

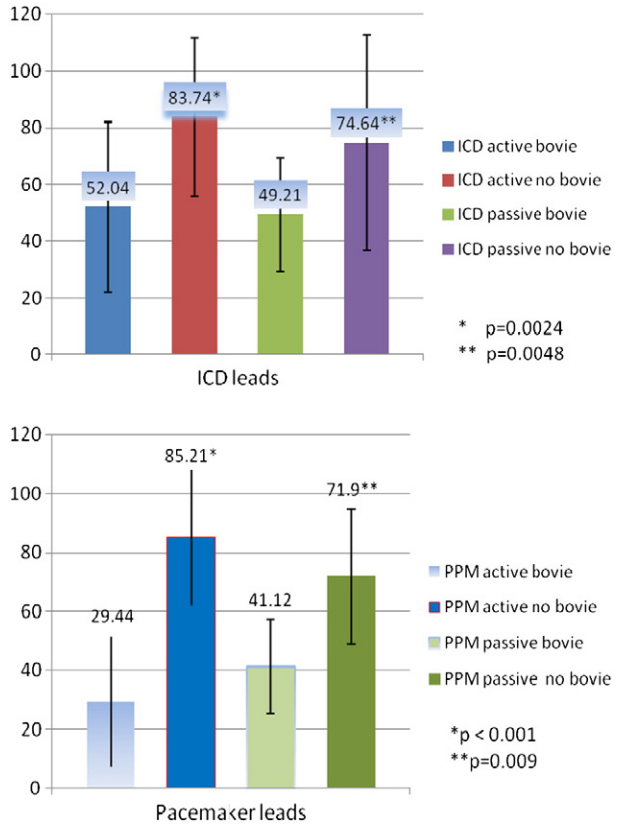

Fig. 1. Force required to manually extract pacemaker and implantable cardioverter-leads in an in vitro model with and without EE application.

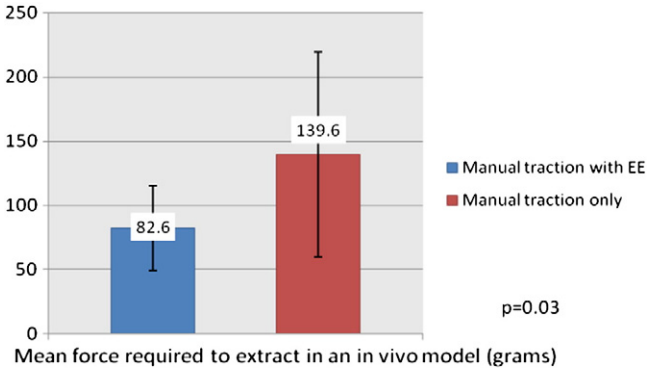

Fig. 2. Force required to manually extract pacemaker and implantable-cardioverter leads in an in vivo model with and without EE application.

3. Results

In the gel model, the average force required for extraction, using manual traction in the active (83.7 g) and passive (74.6 g) fixation ICD leads, was reduced by 37.8% and 33.5%, respectively with EE (both $p < 0.01$). The force required for extraction, using manual traction in the active (85.2 g) and passive (71.9 g) fixation

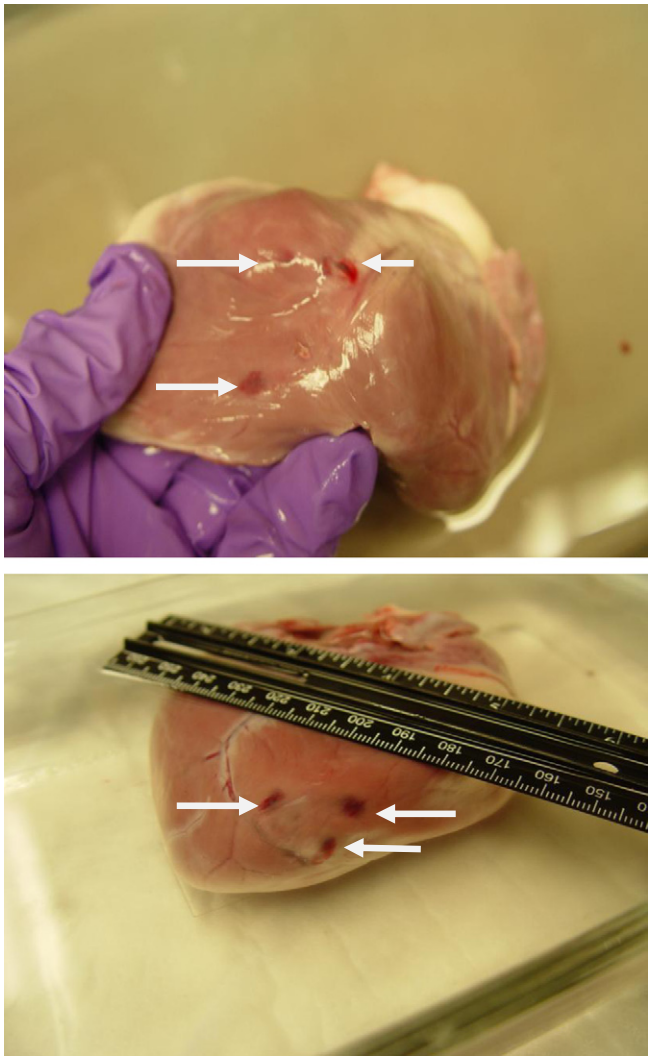

Fig. 3. Post mortem right ventricular site of implantation with accompanying epicardial hemorrhage. Manual traction only (top) and manual traction with EE application (bottom). (Arrows indicate the site of implantation).

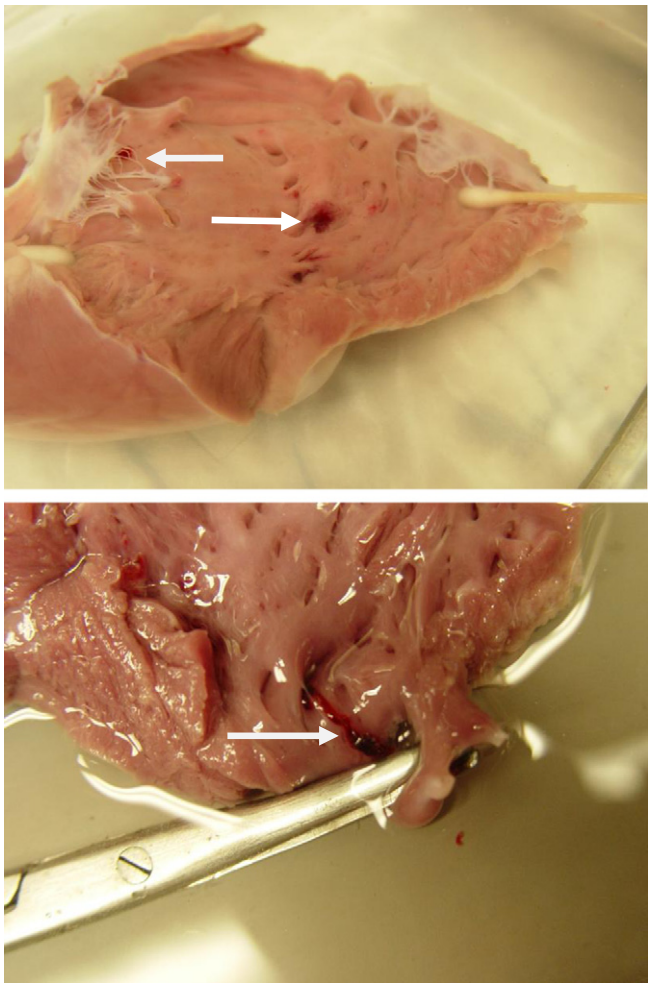

Fig. 4. Post mortem right ventricular site of implantation with accompanying endocardial hemorrhage. Manual traction only (top) and manual traction with EE application (bottom). (Arrows indicate the site of implantation).

pacemaker leads, was reduced by 64.4% and 42.6%, respectively with EE (both $p < 0.01$). Fig. 1 illustrates the force required to manually extract the leads from the gel with and without application of EE.

In the pig model, acute implantation of an active fixation lead and delivery of EE to the cathode ($n = 6$) reduced the force required to manually extract the lead (140 g +/− 32.5 versus 82 g +/− 14.7, $p = 0.03$). Fig. 2 illustrates the force required to manually extract the leads from the pig once acutely implanted with and without EE. Post mortem analysis of the RV displayed formation of an epicardial hemorrhagic lesion that was also present after manual traction and simultaneous delivery of EE (Figs. 3–4). Additional post mortem observations included the absence of pericardial effusion, right ventricular perforation and ventricular arrhythmia.

4. Discussion

Transvenous lead extractions are often complicated by the development of adherent fibrous tissues surrounding the leads. Often this occurs in a heterogeneous pattern predominantly involving defibrillator coils and the cathode pacing tip. While all current extraction methodologies employ some degree of lead traction, innovations including the use of lead locking stylets, stainless steel telescoping sheaths and excimer laser sheaths have significantly improved efficacy and safety [7].

Despite this, limitations continue to exist. Byrd et al. demonstrated that excimer laser assisted lead extraction is effective but carried major complication risks among 301 patients when compared to non-laser methods [9,10]. Once adhesions have been freed from the main body of the lead, the roles of laser and radiofrequency energy-facilitated sheaths are limited. In the case of an active fixation helix, failure to retract the active mechanism of the helix usually indicates fibrous adhesion formation at the lead–myocardial interface. Cano et al. demonstrated that in thirty-one consecutive patients undergoing active-fixation lead removal, there was a 22.5% failure rate of fixation mechanisms failing to retract [8]. At this point the operator is left with applying manual traction to free the distal dip of the lead from the myocardium. As the operator advances closer to the lead–myocardial interface, the risk of laceration increases with energy delivery. Other techniques utilizing novel catheters or energy sources have also been tried. Talreja et al. reported using radiofrequency energy delivered with a steerable ablation catheter to facilitate lead removal. With a short series of RF ablations, the pacemaker lead tip was successfully freed without complication [11].

In clinical situations when application of laser energy has successfully freed a chronically indwelling lead from the vasculature but not the tip, our findings suggest an alternative of just simple traction. By applying electrosurgical energy directly to the IS-1 pin of the lead tip, one is able to selectively deliver pulverizing energy in a site-specific manner thereby focusing the energy only to areas necessary and potentially minimizing energy delivery to neighboring structures. These studies demonstrate a novel technique to facilitate lead extraction and illustrate proof of concept of this methodology as well as proof of safety in a swine in vivo model. An additional advantage of this technique is that this can be performed without introduction of additional catheters and without obtaining additional vascular access for introduction of long sheaths to facilitate catheter manipulation. This potentially carries with it a lower risk of vascular and myocardial catheter related injury.

5. Conclusions

Site-specific delivery of EE to areas of exposed metal along pacemaker and ICD leads decreased the force necessary for lead extraction in an in vitro and in vivo model. More importantly there was no evidence of cardiac complication during or after a successful extraction procedure.

Given our results and demonstration of safety with maximum output of EE delivery, further studies are needed to evaluate its application in clinical care.

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