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Radiofrequency and Cryo-ablation Effect on Transvenous Pacing and Defibrillatory Lead Integrity: An *in vitro* study

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Abstract

Introduction—Medical societies and cardiac implantable electronic devices (CIED) manufacturers recommend avoiding close or direct contact between the body of transvenous leads and ablation catheters used to treat cardiac arrhythmias. These recommendations are made despite the lack of clinical studies. However, the target myocardium for successful ablation can be contiguous to CIED leads.

Methods and Results—We examine *in vitro* the effects of direct application of radiofrequency (RF) and cryo-ablation energy on the integrity and functionality of CIED leads (excluding the pacing electrodes and defibrillation coils). A saline bath was created to mimic the body milieu. CIED leads, including all commercially available lead insulation materials, were connected to a CIED pulse generator and placed in direct contact with ablation catheter in the tissue bath. RF and cryo-ablation energy were delivered under various conditions, including maximal ablation power, temperature and impedance via the RF generator. CIED lead functionality, reflective of conductor integrity, was evaluated through lead impedance monitoring during ablation. CIED leads were then visually inspected, and examined with optic and electron microscopy as per protocol.

A total of 42 leads were studied. All leads showed absence of insulation damage at the site of ablation visually and with microscopy. Lead functionality was also preserved in all leads.

Conclusion—Catheter ablation in contact with CIED leads using radiofrequency or cryo-ablation *in vitro* did not affect lead body integrity and function despite aggressive ablation settings. It may be reasonable to perform ablation in contact with the body of CIED leads when clinically necessary.

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Keywords

catheter ablation; pacemaker; implantable cardioverter defibrillator; cardiac implantable electronic device leads; cryo-ablation

Introduction

Patients with cardiac implantable electronic device (CIED) may require catheter ablation for the management of arrhythmias. CIED pulse generators are typically not adversely affected by exposure to radiofrequency (RF) energy during ablation beyond transient over sensing [1]. CIED leads, on the other hand, may be mechanically dislodged if recently implanted [2] or potentially damaged through close or direct contact with ablation energy source. Lead insulation has been shown to be damaged by the use of RF electrocautery. [3] However, there is scarce data as to whether catheter ablation can significantly damage CIED leads through direct contact. [4]. Therefore, the general consensus among Heart Rhythm Society and American Society of Anesthesiologists members, as well as CIED manufacturers, is to avoid direct contact between ablation catheters and the CIED leads body or distal tip during RF energy application [5–8]. However, the cardiac tissue involved in arrhythmias initiation or maintenance may be in close vicinity or in direct contact with CIED lead body and require catheter ablation to achieve procedural success. In those cases, the risk of lead damage by catheter ablation is unknown. We aimed to study in vitro the consequences of applying RF and cryo-ablation via catheter ablation in direct contact with the body of CIED leads (other than the pacing electrode and defibrillation coils).

Methods

A physiologic bath solution was created to perform in vitro ablation (Figure 1). Several CIED leads were tested to determine if ablation had any impact on the leads' integrity, as well as their functionality and electrical stability. Various settings and powers were used as described below.

Milieu preparation

A preparation was developed to simulate in vivo setting. A saline bath solution was created with media temperature at 37°C with a submersible water heater (United Vet Equine, Eden Prairie, MN). A stainless steel dispersive electrode, similar to the electrode patch used in humans during ablation, was created. The dispersive electrode was immersed in the solution and connected to a conventional RF delivery system. A thick piece of raw chicken breast was positioned on the dispersive electrode. Conductivity in the physiologic bath was ensured with salt to achieve an impedance range similar to that observed in humans (100–250 ohms) [9]. The different leads were positioned in succession on the chicken breast and maintained in position with clips to ensure stability.

A centrifugal mini pump (LP002D2, Foshan Xingwo, Guangdong, China) was used to simulate blood flow around the lead by circulating saline in the tissue bath at a velocity of

1.3 m/sec. Two similar set of experiments were performed, one with and another without circulating flow.

Leads tested

Commercially available cardiac transvenous pacing and defibrillator leads were provided by Boston Scientific (BSC) (Natick, MA) and St. Jude Medical (SJM) (St. Paul, MN). Leads were selected to represent a full spectrum of leads (conventional stylet driven pacemaker leads, defibrillation leads, and over the-wire coronary vein leads) and included the three insulation materials available in the market (Polyurethane 55D [PU55D], silicone rubber [silicone], and a silicone/polyurethane copolymer[Optim®]). The characteristics of the leads tested during this study are shown in Table 1.

Ablation protocol

Each tested lead was placed in contact with the chicken breast tissue in the bath. The ablation catheter was positioned in direct contact with the lead tissue interface using a stable metallic arm that secured its position. Contact of the ablation catheter with the tissue and the CIED lead was ensured visually without measuring contact force (figure 1). Ablation energy was delivered by a conventional RF generator (Stockert70 RF Generator, Diamond Bar, CA) and cryo-energy console (106A3 Cryoconsole, Medtronic, Minneapolis, MN) used in clinical practice. Ablation was performed using the following protocol; a) RF 4 millimeter (mm) tip catheter (Celsius, Biosense-Webster, Diamond Bar, CA) at 35 Watts to a temperature of 65 °C for 60 seconds, b) RF 8mm tip catheter (Celsius DS, Biosense-Webster, Diamond Bar, CA) at 60 watts to a temperature of 60 ° C for 60 seconds, c) RF irrigated 3.5 mm tip catheter (ThermoCool SF Biosense-Webster, Diamond Bar, CA) at 45 watts to a temperature of 45 °C for 60 seconds d) cryo-ablation 6 mm tip catheter (FreezorXtra 227F5, Medtronic , Minneapolis, MN) used to achieve a temperature of – 80°C for 4 minutes. Finally, we used the previously described RF catheters to deliver the highest possible power and temperature as follows; a) RF 4mm tip catheter 50 Watts to a maximal temperature of 80°C for 60 seconds, b) RF 8mm tip catheter 70 Watts to a maximal temperature of 80°C for 60 seconds, c) RF irrigated 3.5 mm tip catheter 50 Watts to a maximal temperature of 50°C for 60 seconds. The impedance for the two parameters “delta impedance cutoff” and “maximum impedance cutoff” were turned off on the RF generator, allowing longer delivery time of power and temperature, without repeated RF generator shutoff due to extreme impedance (or temperature) rise. Temperature was measured at the lead/tissue/catheter interface using a digital thermometer probe (Omega, model HH11B, Stamford, CT, USA) that was held in a stable position using a metallic clip within close vicinity but avoiding direct contact with RF catheter tip. The peak temperature reached during ablation was recorded during each energy application. Each set of ablation was performed twice, with the short axis of the catheter tip either parallel or perpendicular to the long axis of the lead body for each lesion set. Before each ablation lesion, the CIED lead was attached to a functioning pacemaker or defibrillator pulse generator obtained from a previously explanted device after infection. Therefore, all pulse generators carried more than half of the full initial battery charge (no pulse generator was near elective replacement interval or end of life). The CIED lead impedance was measured before, during and after ablation through the device programmer. Two ablation sites were determined for each lead.

Each ablation site was delineated using a permanent marker. On pacemaker leads, sites of ablations were located 2 cm and 7 cm away from the pacing electrode. For defibrillator leads, ablation sites were midway between distal and proximal coils. Once the ablation set was completed, each lead was washed with distilled water to remove crystal salts, dried by air exposure and kept in an individually labeled plastic bag. During the entire study, the leads were manipulated very cautiously, avoiding any harsh contact that could scrape or scratch them. The leads were then examined as described below.

Determination of lead damage

Outer insulation macroscopic and microscopic damage assessment—All leads used were removed from packaging just prior to being tested. Control leads representing the three available insulation materials were examined for a baseline reference without ablation. Damage to each lead segment was classified as follow: no visible changes beside those related to lead imperfection <1 mm (class I), significant damage without breach (class II) and breach of insulation (class III). Close visual inspection with a magnifying glass was initially performed. This was followed by an optic microscopic examination (Nikon Eclipse 80i, Nikon Instruments Inc., Melville, NY; x4 and x10) of all leads. A scanning electron microscope (S-4300, Hitachi, Japan) was also used for leads with highest probability of damage. Gray scale photographs of all lead segments were taken at magnification levels ranging from X80 (i.e. 500 µm resolution) to X3000 (10 µm resolution).

Functional changes—Impedance changes representing conductor integrity were measured before, during and after each ablation lesion. A variation of >10% between the two measures was considered potentially significant.

Additional analysis—Once the study was completed, the leads exposed to high RF energy and cryo-ablation were sent to the manufacturers for additional testing. This included evaluation of outer insulation, electrical testing, continuity testing with electrical impedance to assess conductor continuity and manipulation, and stretching of the leads.

Results

A total of 42 leads were tested with a total of 84 sets of lesions applied. Table 1 summarizes the data and presents the impedance changes and temperature measured at the lead/tissue/ablation catheter interface for the leads tested with maximal power and no circulating flow. Steam pops typically occurred once or twice during high temperatures and power delivery settings in the absence of saline flow with perpendicular catheter orientation. Automatic discontinuation of RF energy due to high temperatures rarely occurred during high power delivery.

Overall, there was no apparent visual damage to the insulation of any of the leads in all settings. Catheter tip orientation on the tissue and lead (parallel vs perpendicular) had no significant impact on any of the measured parameters. Optical microscopy confirmed the absence of any breach to the outer insulation at the sites of ablation (Figure 2). Similar observations were made with scanning electron microscope for the leads analyzed (Figure

3). In addition, the manufacturers' analyses confirmed preserved lead functionality and absence of significant damage to the lead insulation or to the conductor.

Discussion

Main Findings

Catheter ablation (RF and cryo-energy) did not damage any of the three commercially available CIED lead insulation materials (PU55D, co-polymer and silicone) in vitro despite higher power and temperature than routinely used in clinical practice. These findings should reduce the concerns for catheter ablation in close vicinity or in direct contact with a chronically implanted CIED lead body when indicated to achieve procedural success (excluding ablation on the lead tip and defibrillator coils).

CIED lead body and RF energy applications

Only one abstract studied the effect of RF energy on CIED leads [4], where a single power application of 55 W was utilized without obvious lead damage. Our study, in contrast, examined the effects of RF at maximum energy and temperature, as well as the effects of cryo-ablation on three different insulation materials commonly used in clinical practice.

Despite high energy applied in direct contact with leads, no physical or functional damage was observed. The absence of lead damage is explained by the inherent characteristics and properties of the insulation material. Polyurethane is a thermoplastic material with a melting point between 185 to 225 degrees Celsius. Meanwhile, silicone is a thermoset, and once cured to rubber state it cannot be melted or dissolved [3]. Both materials can also withstand low temperatures. While polyurethane has moderate resistance to cold [10], silicone can withstand extremely low temperatures of -100°C and below [11]. Optim®, a co-polymer of both materials, demonstrated superior biostability compared to polyurethane [12] while carrying a higher abrasion resistance compared to silicone [13].

In this study, we achieved measured temperatures above 100°C , far from the melting point of polyurethane. However, in clinical practice, reaching such temperatures is not recommended since it is associated with coagulum formation and steam pops, leading to a rise in impedance and termination of energy application [14]. In the study by Lim et al [3], the peak temperature measured in the middle of the electrocautery blade during RF energy application reached 84°C at highest. The temperature at the tip of the blade, certainly higher, could not be measured because of technical difficulty. Overall, several reasons may explain why insulation material was damaged with RF electrocautery but not with RF ablation. First, RF ablation is distinctly different from the waveform used for RF electrocautery, where high-voltage, short duration pulses with a long duty cycle are designed to promote arcing or coagulum formation [15]. Meanwhile, the RF ablation waveform is a continuous unmodulated sine wave of approximately 550 Hz in a range of 40–60 volts [15]. Therefore, the temperature achieved by RF catheter ablation is much lower than that achieved by RF electrocautery cut mode. Second, resistive heating may play a role in raising temperature around leads during electrocautery use, since leads are encased in tissue, which limits heat dissipation. In contrast, temperature rise next to CIED leads in a bath or in cardiac chambers

is limited by the cooling effect of circulating flow. Meanwhile, the inner metallic conductor integrity was assessed by impedance changes. A significant damage in the conductor would likely have been associated with significant impedance rise, which was never observed in any of the leads.

Clinical practical implications

This study may reduce the concerns to ablate very close or in direct contact with the CIED lead body when indicated. Currently, operators attempt to ablate away from CIED leads. However, in certain instances ablation is needed in close proximity to CIED lead such as cavotricuspid isthmus [16], coronary sinus for atrial tachycardia or non-pulmonary vein triggers [17].

Study limitations

Not all commercially available leads were tested. However, the three commercially available lead insulation materials lead were evaluated. Ablation was not performed within 1cm from the lead tip, since it may increase the sensing and pacing lead properties, possibly through modification of the lead-cardiac tissue interface rather than through direct lead damage [4, 18, 19]. Similarly, no ablation lesions were performed directly on the defibrillation coils since increased lead thresholds [20] and coil impedance fluctuations have been reported [21].

Since this is an in vitro study, it is uncertain whether those results apply in vivo. However, no direct lead damage related to catheter ablation has ever been reported in the literature. Therefore, it may be reasonable to extrapolate those results to humans, although it would be ideal to have an in vivo study, such as an animal study.

Conclusion

Standard and high power RF as well as cryo-energy ablation on transvenous leads (other than defibrillatory coils and lead tip) did not compromise lead insulation, function or electrical stability. Therefore, catheter ablation using RF or cryo-energy may be reasonable on or in close proximity to cardiac transvenous lead body when necessary.

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Abbreviations

CIED	cardiac implantable electronic devices
RF	radiofrequency
RV	right ventricular
CTI	cavotricuspid isthmus
CS	coronary sinus

Figure 1.

Experiment setting included RF generator (A), chicken breast on dispersive electrode in saline bath (B), centrifugal mini pump (C), and submersible water heater (D). Structures numbered in the saline bath as follows; ablation catheter (1), thermometer probe (2) and tested CIED lead (3).

Figure 2.
Representative image of optic microscopy examination of lead at site of ablation showing the absence of insulation damage ($\times 10$).

Figure 3.
Representative image of electron microscopy examination of a tested lead at site of ablation showing the absence of insulation damage ($\times 800$).

Effects of radiofrequency ablation with maximal power using non-irrigated 4mm and 8mm catheters and 3.5 mm continuous irrigation catheter and cryotherapy during non-circulating saline bath on transvenous lead outer insulation and functional and electrical integrity.

Table 1

Lead model	Ablation catheter used	Temperature max (C°)	Visual inspection	Microscopic examination	Lead Impedance change (%)	Continuity testing
Guidant Model 4470 Pacemaker Polyurethane	4 mm	92.2	Class I	(-)	6.3	(-)
	8 mm	94.4	Class I	(-)	0	(-)
	3.5 mm TC *	44.9	Class I	(-)	5.3	(-)
	Cryocatheter	n/a	Class I	(-)	2.2	(-)
Guidant Model 0157 Defibrillator Silicone	4 mm	103.9	Class I	(-)	0	(-)
	8 mm	82.2	Class I	(-)	0	(-)
	3.5 mm TC *	61.1	Class I	(-)	5	(-)
	Cryocatheter	n/a	Class I	(-)	0	(-)
SIM ** Model 1158 T CS [†] lead Co-polymer	4 mm	106.1	Class I	(-)	3.8	(-)
	8 mm	94.4	Class I	(-)	3.6	(-)
	3.5 mm TC *	55.8	Class I	(-)	6.7	(-)
	Cryocatheter	n/a	Class I	(-)	3.2	(-)

* TC=3.5 mm tip continuous irrigation catheter ThermoCool(SF Biosense-Webster, Diamond Bar, CA)

** SIM= St.Jude Medical

[†]CS= Coronary Sinus