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A Novel Defibrillation Tool

Percutaneously Delivered, Partially Insulated Epicardial Defibrillation

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ABSTRACT

OBJECTIVES We aimed to develop a percutaneous defibrillation system with partially insulated epicardial coils to focus electrical energy on the myocardium and prevent or minimize extracardiac stimulation.

BACKGROUND Epicardial defibrillation systems currently require surgical access.

METHODS We tested 2 prototypes created for percutaneous introduction into the pericardial space via a steerable sheath. This testing included a partially insulated defibrillation coil and a defibrillation mesh with a urethane balloon acting as an insulator to the face of the mesh not in contact with the epicardium. The average energy associated with a chance of successful defibrillation 75% of the time was calculated for each experiment.

RESULTS Of 16 animal experiments, 3 pig experiments had malfunctioning mesh prototypes such that results were unreliable; these were excluded. Therefore, 13 animal experiments were analyzed, 6 in canines (29.8 ± 4.0 kg) and 7 in pigs (41.1 ± 4.4 kg). The overall chance of successful defibrillation 75% of the time was 12.8 ± 6.7 J (10.9 ± 9.1 J for canines and 14.4 ± 3.9 J in pigs; $p = 0.37$). The lowest chance of successful defibrillation 75% of the time obtained in canines was 2.5 J, whereas in pigs it was 9.5 J. The lowest energy resulting in successful defibrillation was 2 J in canines and 5 J in pigs. There was no evidence of coronary vessel injury or trauma to extrapericardial structures.

CONCLUSIONS Percutaneous, epicardial defibrillation using a partially insulated coil is feasible and seems to be associated with low defibrillation thresholds. Focusing insulation may limit extracardiac stimulation and potentially lower energy requirements for efficient defibrillation. (J Am Coll Cardiol EP 2017;■:■-■) © 2017 Published by Elsevier on behalf of the American College of Cardiology Foundation.

The developments of the transvenous pacemaker and implantable cardioverter-defibrillator (ICD) stand as 2 of the greatest innovations in cardiology. Despite their life-saving capabilities, the transvenous approach for implantation is associated with numerous limitations and complications. This includes lead-associated tricuspid valve regurgitation, venous thrombosis,

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ABBREVIATIONS AND ACRONYMS

DFT = defibrillation threshold

ED75 = chance of successful defibrillation 75% of the time

ICD = implantable cardioverter defibrillator

VF = ventricular fibrillation

cardiac/vascular perforation, lead thrombus, and cardiac implantable electronic device-associated infection (1-7).

Although some of these complications can be avoided with leadless techniques (8) or subcutaneous placement in the case of ICDs (9), problems remain. Leadless techniques are limited to pacing function only and subcutaneous ICDs are devoid of chronic pacing ability (10,11). Defibrillation coils can be placed epicardially via surgical techniques (12). The surgical approach may be useful in patients with contraindications to transvenous device placement such as venous thrombosis, congenital heart disease-associated anatomic variance and mechanical tricuspid valve. However, surgical placement is associated with significant morbidity, longer duration of hospital stay, and added costs. Therefore, the ability to place epicardial leads without the need for thoracotomy would be a big advance.

Even if these limitations are circumvented, ICD shocks are associated with considerable morbidity secondary to shock-associated pain. Numerous studies have investigated shock pain, although these have predominantly used transvenous defibrillator systems (13-15).

We have previously shown feasibility of partially insulated epicardial pacing leads (16). Thus, we sought to develop an entirely percutaneous defibrillator system coupled with partially insulated epicardial defibrillation leads designed to focus energy on the heart. We hypothesized that this would improve the defibrillation threshold (DFT), thus permitting use of lower shock energy.

METHODS

CATHETER DESIGN. Four animals were used for prototype development and improvement. Because only 1 energy level was tested during prototype refinement, these were not included in the overall analysis. We designed and tested 2 distinct prototypes (50 cm long, 12-F size) with partial insulation. These prototypes were built for percutaneous introduction into the pericardial space via a custom, steerable epicardial sheath (patent number: WO 2015/143327 A1; 7,620,458 B2; US 8,315,716 B2) (**Figure 1**):

- Partially insulated forked lead: The defibrillation coil was made from SS 0.070OD 3-filar coil and partially insulated with a cover of polyether block amide insulation (Pebax, Arkema, King-of-Prussia, Pennsylvania). A radio-opaque marker at the catheter tip helped to define the position with respect to insulation. A modification included a fixation screw made of 0.02-inch-thick stainless steel wire coil wrapped to a 0.075-inch diameter and elongated to 0.15-inch length that may be screwed into the epicardial surface of the heart to improve stability after positioning and defibrillation.
- Partially insulated mesh: The defibrillation mesh was constructed from 0.008-inch stranded nitinol mesh wire. A urethane balloon was attached to the frame and mesh, acting as an insulator to the face of the mesh not in contact with the epicardium.

ELECTROPHYSIOLOGY LABORATORY SETUP. Experiments were performed in dedicated large-animal translational electrophysiology laboratories at Mayo Clinic, Rochester, Minnesota, and at St Anne's University Hospital, Brno, Czech Republic. Electrocardiography recordings were performed using the Cardiolab System (version 6.8.1 release 2, GE Healthcare, Wauwatosa, Wisconsin). High- and low-pass filters were set at 0.05 Hz and 100 Hz, respectively. Sensed signals were gained at 2,500 times as standard.

ANIMAL PREPARATION. The study was approved by the Mayo Clinic Institutional Animal Care and Use Committee and the Ethics Committee of the University of Veterinary and Pharmaceutical Sciences, Brno, Czech Republic. Male mongrel dogs were used at Mayo Clinic, and female swine were used at Brno, Czech Republic. Animals were in the fasting state. All animals were instrumented in an identical fashion. Intravenous ketamine (10 mg/kg) and diazepam (0.5 mg/kg) were used for sedation in canines. Intramuscular telazol (5 mg/kg) and xylazine (2 mg/kg) were used for sedation in swine. After sedation, animals were shaved in the groin, neck, and chest areas, where applicable. Isoflurane (1% to 3%) inhalation anesthetic was used for maintenance of general anesthesia. Continuous surface electrocardiography was performed. Sheaths were placed using Seldinger technique. A 9-F sheath was placed in the left femoral artery for continuous blood pressure monitoring. 9-F sheaths were placed in the femoral veins; in dogs, a 12-F external jugular vein sheath was also placed. An intracardiac echocardiography catheter (AcuNav, Siemens, Washington, DC) was used. Animal body temperature was maintained at 38°C using a dorsal water flow heating pad. Anterior percutaneous epicardial access was obtained using the technique of Sosa et al. (17). Two 18-F sheaths were inserted to permit 2 prototype defibrillator leads to be positioned (**Figure 2**). Prototype leads were introduced into the