JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
© 2017 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

VOL. 70, NO. 5, 2017
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2017.06.008

Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation

Jin Iwasawa, MD,[a] Jacob S. Koruth, MD,[a] Jan Petru, MD,[b] Libor Dujka, MD,[b] Stepan Kralovec,[b] Katerina Mzourkova,[b] Srinivas R. Dukkipati, MD,[a] Petr Neuzil, MD, PhD,[b] Vivek Y. Reddy, MD[a,b]

ABSTRACT

BACKGROUND Saline irrigation improved the safety of radiofrequency (RF) ablation, but the thermal feedback for energy titration is absent.

OBJECTIVES To allow temperature-controlled irrigated ablation, a novel irrigated RF catheter was designed with a diamond-embedded tip (for rapid cooling) and 6 surface thermocouples to reflect tissue temperature. High-resolution electrograms (EGMs) from the split-tip electrode allowed rapid lesion assessment. The authors evaluated the preclinical and clinical performance of this catheter for pulmonary vein (PV) isolation.

METHODS Using the DiamondTemp (DT) catheter, pigs ($n = 6$) underwent discrete atrial ablation in a temperature control mode (60°C/50 W) until there was ~80% EGM amplitude reduction. In a single-center clinical feasibility study, 35 patients underwent PV isolation with the DT catheter (study group); patients were planned for PV remapping after 3 months, regardless of symptomatology. A control group included 35 patients who underwent PV isolation with a standard force-sensing catheter.

RESULTS Porcine lesion histology revealed transmurality in 51 of 55 lesions (92.7%). In patients, all PVs were successfully isolated; no char or thrombus formation was observed. Compared with the control group, the study cohort had shorter mean RF application duration (26.3 ± 5.2 min vs. 89.2 ± 27.2 min; $p < 0.001$), shorter mean fluoroscopic time (11.2 ± 8.5 min vs. 19.5 ± 6.8 min; $p < 0.001$), and lower acute dormant PV reconduction (0 of 35 vs. 5 of 35; $p = 0.024$). At 3 months, 23 patients underwent remapping: 39 of 46 PV pairs (84.8%) remained durably isolated in 17 of these patients (73.9%).

CONCLUSIONS This first-in-human series demonstrated that temperature-controlled irrigated ablation produced rapid, efficient, and durable PV isolation. (ACT DiamondTemp Temperature-Controlled and Contact Sensing RF Ablation Clinical Trial for Atrial Fibrillation [TRAC-AF]; NCT02821351) (J Am Coll Cardiol 2017;70:542–53)

Pulmonary vein (PV) isolation is the mainstay of catheter ablation for patients with atrial fibrillation (AF) (1). Technological advances, such as balloon catheters to facilitate PV isolation, are increasingly being used (2,3). However, point-by-point radiofrequency (RF) ablation catheters remain the most frequently used technology, largely because of the greater flexibility of the lesion set that can be deployed. Although conceptually straightforward, placing contiguous and transmural point-by-point RF lesions around the PVs is technically challenging. This is supported by the reported near-universal presence of PV reconnections in redo-AF ablation cases and the low rate of durable PV isolation observed in the

Listen to this manuscript's audio summary by *JACC* Editor-in-Chief Dr. Valentin Fuster.

From the [a]Helmsley Electrophysiology Center, Mount Sinai Medical Center, New York, New York; and the [b]Na Homolce Hospital, Prague, Czech Republic. Drs. Koruth and Neuzil have received research grant support from Advanced Cardiac Therapeutics, Inc. Dr. Reddy has served as a consultant to and has received research grant support from Advanced Cardiac Therapeutics, Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Andrea Natale, MD, served as Guest Editor for this paper.

Manuscript received March 13, 2017; revised manuscript received May 2, 2017, accepted June 1, 2017.

GAP-AF study (4–7). From a safety perspective, the advent of saline irrigation has decreased the incidence of thrombus and char formation on the ablation tip. However, saline irrigation on current ablation catheters also precludes temperature feedback, so these catheters are typically operated in a power control mode.

SEE PAGE 554

It is in this context that we investigated the DiamondTemp (DT) ablation catheter (Advanced Cardiac Therapeutics, Inc., Santa Clara, California), a composite-tip, diamond-embedded, temperature-sensing, saline-irrigated RF ablation catheter. The catheter has 6 insulated thermocouples on the ablation tip surface to directly measure the tissue surface temperature, thereby potentiating temperature-guided irrigated ablation. To provide rapid diffusion of heat, the ablation tip is embedded with industrial-grade diamond, a material with a thermal diffusivity that is 2 orders of magnitude higher than platinum. Finally, instead of the standard 3.5- or 4-mm distal ablation electrode, the DT catheter distal electrode is a composite tip to provide higher resolution electrograms (EGMs). During RF delivery, the composite tip behaves as a single RF electrode. Herein, we report our pre-clinical and first-in-human clinical experience using this novel temperature-controlled irrigated RF ablation catheter.

METHODS

This catheter was evaluated in 2 phases. The pre-clinical phase involved electrophysiological and histological assessment of ablation lesions created by this catheter in a series of porcine experiments. The clinical phase involved a single-center evaluation in the TRAC-AF (ACT DiamondTemp Temperature-Controlled and Contact Sensing RF Ablation Clinical Trial for Atrial Fibrillation) trial. In this prospective first-in-human study, patients underwent PV isolation with the DT catheter to treat paroxysmal AF, along with a pre-specified PV remapping procedure at ~3 months regardless of intervening symptomatology. Thus, in addition to the acute procedural performance of the catheter, we also assessed the 3-month durability of electrical PV isolation. With regard to the procedural performance, the TRAC-AF outcomes were compared with another retrospective cohort of patients with paroxysmal AF who underwent PV isolation using a standard force-sensing irrigated catheter at Mount Sinai Hospital (New York, New York).

The preclinical experiments were approved by the Institutional Animal Care and Use Committees at Mount Sinai Hospital, and the clinical phase was approved by the human ethics committee at Homolka Hospital, Prague, Czech Republic, and by the Czech Republic Competent Authority, SUKL (State Institute for Drug Control). Written informed consent was obtained from all patients. The authors had full access to and take full responsibility for the integrity of the data, and agree to this paper as written.

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation
CF = contact force
DT = DiamondTemp
EGM = electrogram
PV = pulmonary vein
RF = radiofrequency

CATHETER DESIGN. The diamond-tip irrigated DT catheter is a 7.5-F externally irrigated catheter designed to deliver RF energy via a 4.1-mm catheter tip electrode (Figure 1). The tip segment consists of a composite tip electrode and 2 ring electrodes, all made of platinum-iridium. Unique to the catheter's design, the 2-part composite ablation electrode tip is embedded with 2 industrial-grade diamonds, interconnected at the distal tip electrode, which allow rapid heat shunting by virtue of their high thermal diffusivity. This permits accurate temperature estimation along the entire length of the electrode. The distal aspect of the composite electrode is 0.6 mm and has 6 irrigation ports. By allowing effective cooling, the diamonds reduce the irrigation rate to 8 ml/min during ablation. Although the dual composite ablation tip acts as a single electrode during ablation, the 2 aspects of this tip are electrically insulated to allow for high-resolution EGM sensing separately.

Finally, there are 3 surface thermocouples at the distal end and 3 thermocouples at the proximal end to monitor the tip–tissue interface temperature during irrigated ablation (Figure 1). A custom RF generator (Advanced Cardiac Therapeutics) delivers RF energy in a temperature-control mode. The temperature recording capability was validated in a bench-top model consisting of irrigated ablation on fresh porcine hearts. Temperature sensors were inserted into the target tissue adjacent to the ablation catheter. The catheter temperature was set to 55°C and 60°C (i.e., maximum surface thermocouple temperature) with contact force (CF) between 12 and 15*g*, and ablation performed in temperature-control mode. In a series of 20 ablation runs, the average study catheter set temperature of 58.5°C corresponded to a mean tissue temperature of 64.2°C at 1-mm depth. This difference between the surface recording and recording at 1-mm depth was consistent with the nature of irrigated ablation that drives the hot spot of RF ablation deeper into the tissue.

PRECLINICAL STUDY. After an overnight fast, percutaneous venous access was obtained in 6 pigs;