Predictability of lesion durability for AF ablation using phased radiofrequency: Power, temperature, and duration impact creation of transmural lesions

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BACKGROUND Long-term clinical outcomes for atrial fibrillation ablation depend on the creation of durable transmural lesions during pulmonary vein isolation and on substrate modification. Focal conventional radiofrequency (RF) ablation studies have demonstrated that tissue temperature and power are important factors for lesion formation. However, the impact and predictability of temperature and power on contiguous, transmural lesion formation with a phased RF system has not been described.

OBJECTIVE The purpose of this study was to determine the sensitivity, specificity, and predictability of power and temperature to create contiguous, transmural lesions with the temperature-controlled, multielectrode phased RF PVAC GOLD catheter.

METHODS Single ablations with the PVAC GOLD catheter were performed in the superior vena cava of 22 pigs. Ablations from 198 PVAC GOLD electrodes were evaluated by gross examination and histopathology for lesion transmurality and contiguity. Lesions were compared to temperature and power data from the phased RF GENius generator. Effective contact was defined as electrodes with a temperature of ≥50°C and a power of ≥3 W.

RESULTS Eighty-five percent (168 of 198) of the lesions were transmural and 79% (106 of 134) were contiguous. Electrode analysis showed that >30 seconds of effective contact identified transmural lesions with 85% sensitivity (95% confidence interval [CI] 78%–89%), 93% specificity (95% CI 76%–99%), and 99% positive predictive value (95% CI 94%–100%). Sensitivity for lesion contiguity was 95% (95% CI 89%–98%), with 62% specificity (95% CI 42%–78%) and 90% positive predictive value (95% CI 83%–95%). No char or coagulum was observed on the catheter or tissue.

CONCLUSION PVAC GOLD safely, effectively, and predictably creates transmural and contiguous lesions.

KEYWORDS Atrial fibrillation; Ablation; Lesion; Pulmonary vein isolation; PVAC GOLD; Radiofrequency; Transmural; Contiguous

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Introduction

The creation of contiguous, transmural lesions is central to an effective ablation treatment for atrial fibrillation (AF). Non-transmural lesions or gaps can lead to AF recurrence and other atrial tachyarrythmias.[1] Strategies have been developed to assess ablation lesion contiguity and transmurality that include impedance changes, 3-dimensional mapping, intracardiac electrocardiographic changes, contact force, magnetic resonance imaging, ultrasound, and photoacoustic.[2–7] However, the prediction of whether ablation has created a durable lesion is an ongoing challenge.

Studies[8,9] of conventional radiofrequency (RF) ablation have demonstrated that tissue temperature, RF power, and electrode-tissue contact are important factors for lesion formation. Lesions are generated by irreversible cardiac tissue damage occurring at temperatures above 50°C.[10–12] Active cooling through irrigation was introduced into conventional RF ablation catheters to deliver sufficient power to achieve irreversible tissue damage and reduce the production of char and coagulum.[8] In addition, 3-dimensional mapping and navigation systems have been developed to assist in the creation of contiguous lesions. More recently, contact force sensing has been added to facilitate the prediction of creating transmural lesions and decrease the incidence of pericardial effusion.[4]

Multielectrode catheters have been developed to create long, contiguous lesions more efficiently and effectively than with focal catheters. A previous study[13] of multielectrode catheters showed that a single large contiguous lesion is created by simultaneously ablating with adjacent electrodes. In addition,

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McRury et al[13] demonstrated that pulsed energy delivery was more efficient at generating deeper lesions than was conventional RF delivery. The phased RF system with the multielectrode PVAC GOLD catheter (Medtronic, Minneapolis, MN) uses a similar energy delivery process by duty cycling the phased RF energy. This multielectrode system simultaneously delivers pulses of unipolar and bipolar energy through multiple electrodes to efficiently create contiguous, transmural lesions.[14,15]

The temperature-controlled phased RF system uses a multifactorial nonirrigated approach to cool electrodes in order to deliver sufficient power for lesion generation without producing char or coagulum.[14,15] This multifactorial cooling approach uses the combined effect of energy duty cycling,[16] convective blood flow, gold electrodes,[17] and increased temperature accuracy to maintain adequate electrode cooling. A previous study[18] of the phased RF system has demonstrated that delivering ≥3 W of power while maintaining adequate temperature was associated with decreased pulmonary vein reconnection and good clinical outcomes.

The purpose of this study was to evaluate the correlation between RF power and electrode temperature with the creation of contiguous, transmural lesions using the multielectrode PVAC GOLD catheter.

Methods

Porcine ablation model

The porcine ablation model has been previously described.[15,19] Briefly, pigs underwent sedation and general anesthesia followed by femoral vein insertion of a fixed curve sheath (Arrive 10F, Medtronic, Minneapolis, MN). Heparin was administered in a 10,000–15,000 IU bolus at the beginning of the procedure, and a continuous infusion of 150 mL/h (100 IU/mL) was performed to maintain an Activated Clotting Time (ACT) of ≥350 seconds. Activated clotting times were measured every 30 minutes during the procedure using the ACT Plus system (Medtronic). All ablation procedures were performed using the PVAC GOLD catheter and GENius generator v.15.1 (Medtronic). Twenty-two pigs were studied (16 pigs sacrificed on the day of ablation to study acute lesion formation and 6 pigs sacrificed 2 weeks after ablation to study chronic lesion formation). The study protocol was reviewed and approved by the Institutional Animal Care and Use Committee.

Single superior vena cava placements and ablations

The PVAC GOLD catheter was maneuvered using fluoroscopy and electrograms into the muscular section of the superior vena cava (SVC). The phased RF system including the PVAC catheter has been previously described.[14,20] Briefly, the temperature-controlled GENius generator delivers simultaneous bipolar and unipolar phased RF energy to all or selected electrode pairs on the 9-electrode PVAC GOLD catheter with a maximum of 10 W per electrode. To assess the impact on lesion contiguity and transmurality, only a single SVC ablation was performed in each pig, with phased RF energy (unipolar and bipolar) delivered to all 9 electrodes for 60 seconds. After ablation, each electrode (n = 198) was inspected for adhered char or coagulum.

Lesion transmurality and contiguity analysis

After ablation, pigs were sacrificed (on the day of ablation or 2 weeks after ablation) and the entire SVC was removed. Ablation lesions were identified and measured after staining with triphenyl tetrazolium chloride. Lesions at electrode sites and spaces between electrode sites were categorized as either "absent/partial" or "transmural." Acute lesions were determined to be transmural if either contraction-band necrosis (appears red on gross examination) or coagulative necrosis (appears beige on gross examination) occurred through the full thickness of tissue. Chronic lesions were determined to be transmural if replacement fibrosis occurred through the full thickness of tissue. The tissue thickness under each electrode was measured postablation. Tissue was also evaluated for evidence of char or coagulum production.

Correlation of lesion efficacy and biophysical parameters

Lesion transmurality underneath and between electrodes was compared to the electrode power and temperature for each electrode. The phased RF GENius generator includes a temperature and power algorithm (Contact IQ) with thresholds of ≥50°C and ≥3 W. *Effective contact* was thus defined as the cumulative time (in seconds) an electrode was at a temperature of ≥50°C associated with irreversible tissue damage and a power delivery of ≥3 W associated with decreased pulmonary vein reconnection.[18] The transmurality of each lesion was correlated with the effective contact duration for each electrode.

Histopathology

Tissue was dissected and embedded in paraffin, sectioned (3–6 μm), and stained with hematoxylin & eosin and Masson trichrome. The intimal and adventitia aspects of the SVC were examined, and the following pathologic parameters were assessed: granulation tissue and/or fibrosis, intimal appearance (thrombus), inflammation, transmurality of damaged or replacement tissue, and the condition of the surrounding tissues.

Statistical analysis

Sensitivity, specificity, positive predictive value, and negative predictive value were calculated for the lesion algorithm of ≥30 seconds of effective contact to predict lesion transmurality and contiguity. *True positives* were defined as histologically verified transmural lesions under each electrode ('transmural") or between 2 adjacent electrodes ("contiguous"), with each electrode having ≥30 seconds of effective contact. *True negatives* were defined as histologically verified nontransmural or noncontiguous lesions under each electrode or between 2 adjacent electrodes with one or both adjacent electrodes having <30 seconds of effective contact. A *false positive* was a nontransmural or noncontiguous lesion that had ≥30 seconds of effective contact on one or both adjacent electrodes. A *false negative* was a transmural and contiguous lesion that had <30 seconds of effective contact on one or both adjacent electrodes. The 95% confidence intervals were calculated