Optimal conditions for high-power, short-duration radiofrequency ablation using a novel, flexible-tipped, force-sensing catheter

Jonathan P. Piccini, MD, MHS, FHRS,* Amish S. Dave, MD, PhD,† Douglas S. Holmes, MD,‡ Jeffrey R. Winterfield, MD,§ John H. Tranter, MSEE,‖ Catherine Pipenhagen, BS,‖ L. Boyce Moon, BS,‖ Nicholas M. Ambrosius, BS,‖ Jed A. Overmann, DVM, MS, DACVP,‖ Hana Boudlali, MS,‖ Riki Thao, AOT,‖ Chris Geurkink, BE,‖ Zada Thamavong, AAS,‖ James A. Jensen, PhD,‖ Jeffrey M. Fish, DVM‖

*From the *Electrophysiology Section, Duke University Hospital, Durham, North Carolina, †Houston Methodist DeBakey Cardiology Associates, Houston, Texas, ‡Department of Medicine, NYU Grossman School of Medicine, New York, New York, §Department of Medicine, Medical University of South Carolina, Charleston, South Carolina, and ‖Abbott, St. Paul, Minnesota.*

BACKGROUND High-power, short-duration (HPSD) radiofrequency ablation (RFA) reduces procedure time; however, safety and efficacy thresholds vary with catheter design.

OBJECTIVE The study sought to determine optimal HPSD ablation conditions with a novel flexible-tipped, contact force–sensing RFA catheter.

METHODS RFA lesions were created in thigh muscle (16 swine) over a range of conditions (51–82 W, 2–40 g, 8–40 mL/min irrigation). An intracardiac study was performed (12 swine) to characterize steam pop thresholds. Lesions were created in a second intracardiac study (14 swine, n = 290 pulmonary vein isolation [PVI] lesions) with combinations of radiofrequency power, duration, and contact force. PVI was tested, animals were sacrificed, and lesions were measured.

RESULTS The likelihood of coagulation formation in the thigh model was <20% when power was ≤79 W, when contact force was ≤40 g, when duration was ≤11 seconds, and when irrigation rates were 8 to 40 mL/min. The impact of contact force on lesion safety and efficacy was more pronounced using HPSD (60 W/8 seconds) compared with conventional ablation (30 W/45 seconds) (P = .038). During PVI, focal atrial lesions ranged in width from 4.2 to 12.5 mm and were transmural 80.8% of the time. PVI was achieved in 13 of 14 veins. Logistic regression identified that the optimal parameters for radiofrequency application were 60 to 70 W with a duration <8 seconds and <15 g contact force.

CONCLUSIONS Optimal HPSD lesions with this this flexible-tipped, force-sensing RFA catheter were created at 60 to 70 W for <8 seconds with <15 g contact force. Chronic studies are ongoing to assess radiofrequency parameter refinements and long-term lesion durability using these conditions.

KEYWORDS Catheter ablation; Radiofrequency ablation; Biophysics; Lesion formation; Contact force; Atrial fibrillation

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Introduction

Radiofrequency (RF) ablation remains the primary energy modality for catheter ablation of atrial fibrillation (AF). Effective RF ablation is dependent on the ability to create consistent and durable transmural lesions. Power and energy delivery can be increased to improve the likelihood of effective lesion formation, but doing so may augment the risk of injury to adjacent tissue and other complications. One approach to maximize efficacy and improve safety is high-power, short-duration (HPSD) ablation.

Preclinical work has suggested that HPSD improves lesion uniformity, continuity, and transmurality.[1] Similarly, clinical investigation has shown that HPSD ablation leads to more efficient and effective lesion formation when compared with conventional ablation, leading to significant reduction in ablation time.[2,3] The application of HPSD with 45 to 50 W appears to be safe with a relatively low rate of complications.[4] However, HPSD has also been associated with higher rates of arrhythmia recurrence,[3] and the optimal parameters for HPSD (or ultra HPSD) ablation have not yet been determined. Higher power does carry potential risks,

Address reprint requests and correspondence: Dr Jonathan P. Piccini, Electrophysiology Section, Duke Heart Center, Duke Clinical Research Institute, Duke Box 31115, Durham, NC 27701. E-mail address: jonathan.piccini@duke.edu; Twitter: @JonPicciniSr

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KEY FINDINGS

- Safe and effective high-power, short-duration lesions can be created using a novel, flexible-tipped, force-sensing radiofrequency irrigated ablation catheter.
- Contact force has greater impact on safety and efficacy with high-power, short-duration radiofrequency ablation compared with conventional ablation.
- Optimal safety and efficacy with high power and short duration with a flexible-tipped force-sensing catheter were created at 60 to 70 W for <8 seconds with <15 g contact force.

including increased risk of steam pops, perforation, coagulum and char formation, and injury to adjacent structures.

Flexible-tip catheters may have advantages in the delivery of RF energy. First, the flexible tip results in directed irrigation, which may reduce the risk of steam pops.[5] Flexible tips also have greater ability to conform to anatomy and may help avoid excessive contact force. The objective of this analysis was to systematically determine the optimal parameters to maximize the safety and efficacy of HPSD ablation with a novel flexible-tipped, contact force–sensing ablation catheter. Accordingly, we performed a series of ex vivo and in vivo porcine experiments with a wide range of HPSD parameters and contact force to assess differences in lesion formation.

Methods

Study design and RF parameters

The goal of the study was to systematically determine optimal HPSD ablation conditions for safety and efficacy with a novel flexible-tipped, contact force–sensing RF ablation catheter. The study protocol was approved by the Institutional Animal Care and Use Committee and conforms to the Guide for the Care and Use of Laboratory Animals. The catheter under study in this series of analyses was the TactiFlex Ablation Catheter, Sensor Enabled (SE) (Abbott, Minneapolis, MN) (Supplemental Figure 1), which utilizes a flexible tip with fiber optic–based contact force sensor. There are 2 parallel semireflective mirrors in the catheter tip; when force is applied to the tip, the reflected light is perturbed. This perturbation is converted to force magnitude and direction. Bench ex vivo ablation studies were performed to observe efficacy (lesion dimension) and safety (likelihood of steam pop formation). Following these studies, additional in vivo thigh model and intracardiac studies were performed to further refine the optimal parameters for safety and efficacy of HPSD. The overall study design used a sequential and phased approach and is shown in Figure 1. The initial parameter space of RF ablation parameters included target RF power, target force, duration of ablation, irrigation rate, temperature limits, and ramp rate; the following ranges were considered as shown in Figure 1.

Ex vivo bench testing

Bovine hearts were obtained for bench experiments. RF ablation lesions were created on nonperfused bovine right ventricular free wall submersed in saline solution (37°C, electrical conductivity 6.5–7.0 mS/cm) using the TactiFlex SE catheter. For the first bench testing series, random combinations of all ablation parameters uniformly subsampled from the ranges listed in Figure 1 except for duration were tested. Ablation at these combinations of conditions continued until a steam pop occurred, the time of which was recorded. Each trial was assigned a binary code pertaining to the steam pop time; for trials with RF powers between 51 and 69 W, 1 was assigned if the steam pop time was at least 7 seconds (0 was assigned otherwise). For trials with RF powers exceeding 69 W, the steam pop time threshold for assignment of a value 1 was 5 seconds. These thresholds were informed by previous bench investigations in which one could be assured that a lesion of sufficient width and depth could be created (to be confirmed by the subsequent bench efficacy study, described in the following paragraph). A logistic regression model was applied to the previous binary coding vs RF power, target force, and irrigation rate; parameter combinations that yielded a steam pop likelihood of >30% were excluded from consideration (Supplemental Section I). Although 30% is certainly a high-likelihood threshold (even when considering the sensitivity of the bench model), this threshold ensures that a sufficiently large parameter space will remain for the subsequent testing steps in the phased design, such that likelihood models can be extrapolated.

In the second series of bench testing, lesions were created at random combinations of all ablation parameters across the design space remaining after the first bench series. Steam pop occurrences and time of pop were documented. Following RF energy delivery, maximum surface diameter, maximum lesion diameter, and maximum depth were measured for all lesions excluding the ones in which a steam pop occurred. Lesions from RF applications resulting in steam pop were excluded because steam pop occurrence often distorts the tissue making accurate lesion measurement difficult. A logistic regression model was created to determine the likelihood of a lesion having a maximum diameter of at least 6 mm and a depth of at least 3 mm (Supplemental Section II). The identified parameter space was then investigated using the swine thigh model (Figure 1).

Thigh muscle preparation

Each swine was anesthetized using Telazol-xylazine for induction and isoflurane for maintenance of anesthesia. The animals were mechanically ventilated during the entirety of the procedure. Surface electrodes were positioned to continuously monitor the subject's heart rate, and a pulse oximeter was applied to the tongue to verify pulmonary function. An arterial line was placed at a site (at the discretion of the surgeon) for arterial blood pressure monitoring and as a blood collection site. Two ablation return patches were placed on

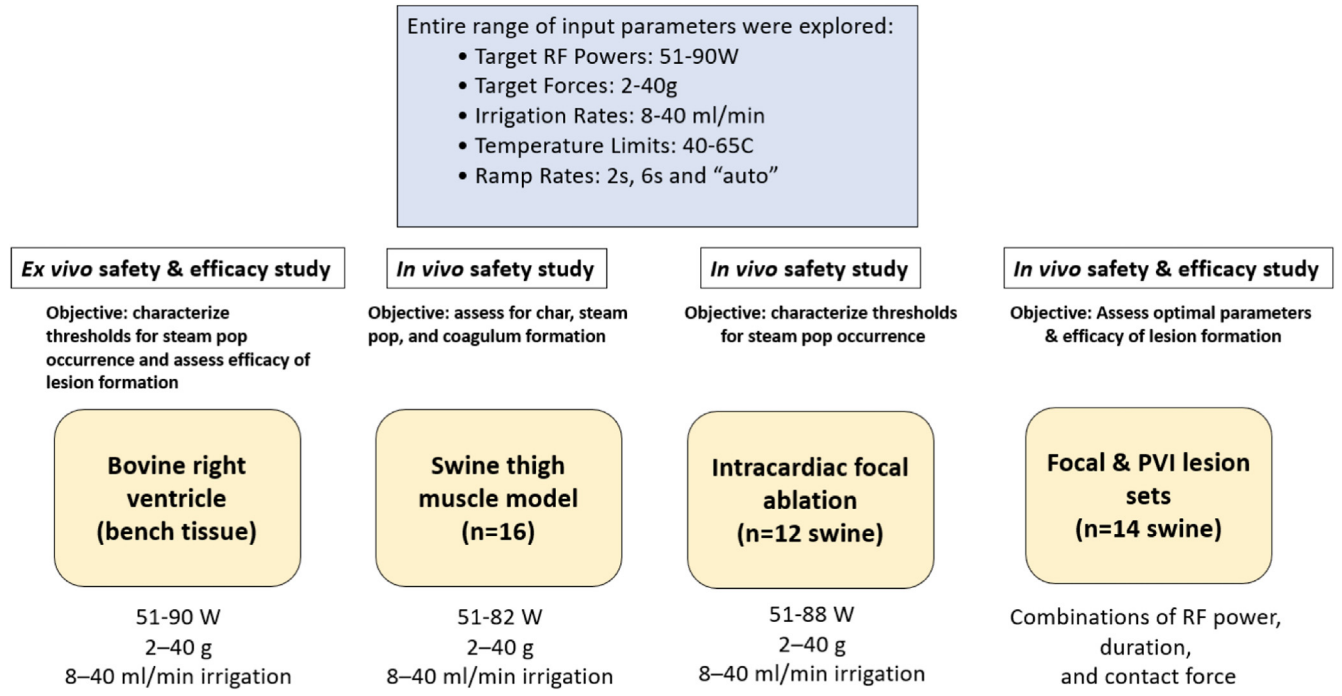

Figure 1 The study design included 3 series of in vivo experiments, in which a wide range of ablation parameters were investigated, as shown in the blue box. In the first study in vivo study, radiofrequency (RF) ablation lesions were created in a swine thigh muscle model to determine adverse event occurrence and lesion size over a wide range of conditions. An intracardiac study was performed to characterize thresholds for steam pop occurrence. In a second intracardiac study, focal and pulmonary vein lesion sets were created with combinations of RF power, duration, and contact force. Pulmonary vein isolation (PVI) was tested post-ablation and animals were sacrificed and lesions were measured.

the animal's skin and connected to the RF generator, allowing the system impedance to be adjusted to approximately 100 Ω. An incision was made over the surface of the biceps femoris. The overlying skin and adipose tissue were gently dissected back to expose the smooth membrane covering the muscle. The skin was pulled back and secured to the corresponding point on a skin cradle apparatus to form a cradle.

A plastic bag containing warm water (above 40°C) was placed directly on the thigh muscle, with the temperature probe inserted into the thigh tissue. The purpose of the warming bag was to increase the tissue to at least 35.5°C, to obtain a temperature in line with those observed in vivo. After removal of the warming bag, the cradle exposing the thigh muscle was filled with 300 to 500 cm^3 of heparinized blood taken from the same animal through the arterial access. The heparinized blood pool used for the procedure had an activated clotting time above 300 seconds, measured every 30 to 45 minutes throughout the procedure.

RF ablation lesions were created using random combinations of ablation parameters uniformly subsampled over the truncated design space remaining after the bench study. Occurrence of steam pop, char, and coagulum were recorded, and binary logistic regression models were created to predict the incidence of adverse event occurrence for the ablation parameters considered (Supplemental Section III). Only the parameter space in which adverse event occurrences were $\leq$20% was considered in subsequent development phases. A threshold of 20% was chosen because the thigh model is quite sensitive to coagulum formation (absence of false negatives). Because thresholds are based on log likelihood models, the model does not cover 0% incidence—there's always some nonzero level of adverse events in the model. Finally, this threshold allowed the subsequent in vivo safety and efficacy studies to be conducted over a sufficiently informative parameter space.

Intracardiac safety and efficacy studies

Prior to the study, each animal was administered 7 days of daily oral amiodarone (approximately 600 mg once per day) to prevent precipitation of ventricular arrhythmias during ablation. Each animal was admitted to the study laboratory in the postabsorptive state. After appropriate skin preparation, 2 ablation return patches, NavX patches (St. Jude Medical, St. Paul, MN), electrocardiography electrodes, and external defibrillation pads were placed. Additionally, 2 electronic stethoscopes were adhered to the chest surface to monitor for steam pops. A rectal probe was used to monitor the animal's body temperature, and a combination of a heated pad and blanket covering was used to maintain the animal's body temperature at or near 37°C. An intracardiac echocardiography catheter was placed in the superior vena cava and a Millar (Houston, TX) pressure monitoring catheter was placed in the aorta. The EnSite Precision Cardiac Mapping System (Abbott) was utilized for all intracardiac studies. Pressure waveforms from the Millar catheter as well as audio waveforms from the stethoscopes were analyzed for the presence of high-frequency spikes occurring on the waveforms

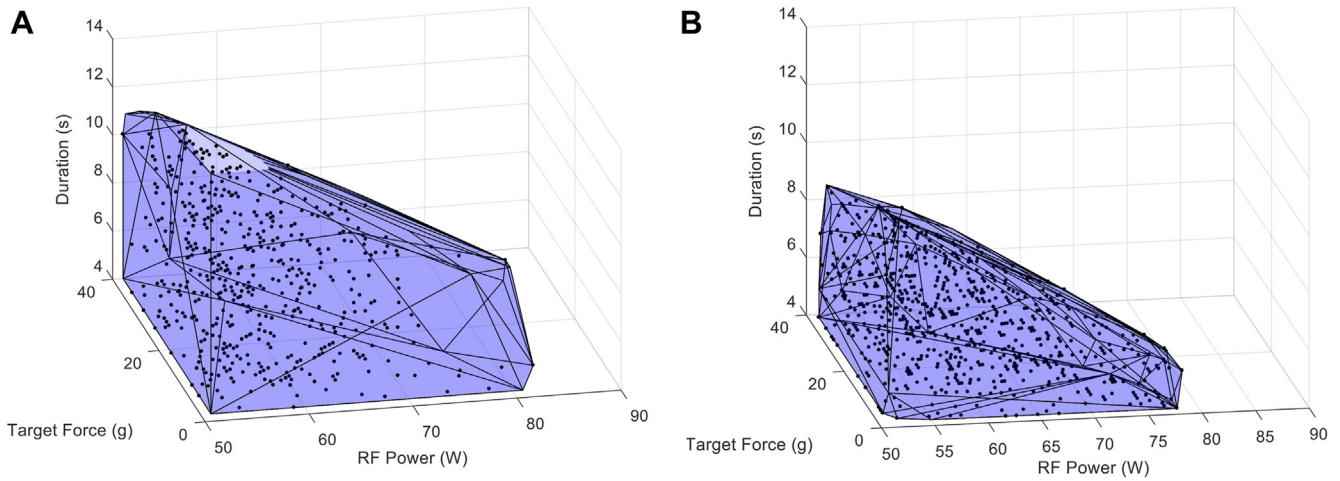

Figure 2 **A:** Three-dimensional space considering the 3 most-dominant factors (radiofrequency [RF] power, duration, and target force); resulting space from bench efficacy study. **B:** Three-dimensional space considering the 3 most dominant factors (RF power, duration, and target force); reduced space from thigh safety study.

from both systems simultaneously in order to allow a high sensitivity for steam pop detection.[6]

Safety study

In this cohort of 12 animals, lesions were created in all 4 cardiac chambers using random combinations of ablation conditions (except duration) subsampled within the truncated parameter space identified during the bench and thigh testing phases. RF ablation was continued until steam pop occurrence or 30 seconds, whichever occurred first. Comparisons with conventional ablation leveraged historical data from a canine ventricular lesion modeling study (rather than in the same cohort of animals as the HPSD ablations).

Efficacy study

Focal lesions at ablation conditions determined by the previous study series were created in the right atria of 16 animals. Subsequently, pulmonary vein isolations (PVIs) were attempted using ablation conditions determined to have a low likelihood of steam pop occurrence; encirclements were performed around the left superior/inferior and right superior/inferior pulmonary veins. A single ablation condition was used for each PVI attempt. After euthanasia, cardiac tissue was perfusion stained using tetrazolium chloride and fixed in 10% neutral buffered formalin. Digital pictures of the atrial lesions were taken from both the epicardial and endocardial surface and the lesion diameter on each surface was digitally measured. For the PVI lesion sets, 3 to 8 full-thickness slices were collected from each pulmonary vein site and assessed histologically (Masson's trichrome) for both transmurality as well as the presence of thrombus.

Statistical analysis

Regression models were created from the data at each step of development. For continuous outcomes such as time to steam pop occurrence, multiple linear regression was used. Binary logistic regression was used to analyze categorical data. Statistical significance was declared at $P < .05$. All statistical analyses were performed with Minitab 18 (Minitab, State College, PA) and MATLAB 2018b (The MathWorks, Natick, MA).

Results

Ex vivo bench study

In the ex vivo experiments, a total of 972 RF ablation lesions were created in order to restrict the range of optimal parameters to be tested in the subsequent in vivo models (Figure 2A).

In vivo thigh safety study

A total of 576 RF ablation lesions created on the thighs of 16 animals were used to establish likelihood of coagulum and char formation across a variety of ablation conditions (Figure 2A). Power output varied from 51 to 82 W, contact force ranged from 2 to 40 g, and the irrigation rates varied from 8 to 40 mL/min. Supplemental Figure 2 illustrates several examples of coagulum formation. A logistic regression model with 4 factors indicated that the likelihood of coagulation formation was <20% when power was ≤79 W, contact force was ≤40 g, duration was ≤11 seconds, and irrigation rates were between 8 and 40 mL/min (Figure 2B). A threshold of 20% was selected because some occurrence of coagulum in the thigh model occurs with irrigated ablation catheters approved for clinical use.

In vivo safety study

The in vivo safety study characterized thresholds for steam pop occurrence in 12 swine. Steam pop detection was enhanced with digital stethoscopes and Millar catheters. Supplemental Figure 3 illustrates several cases of steam pop formation. Logistic regression was used to identify combinations of RF power and contact force in which steam pops were unlikely to occur at durations <15 seconds. The data

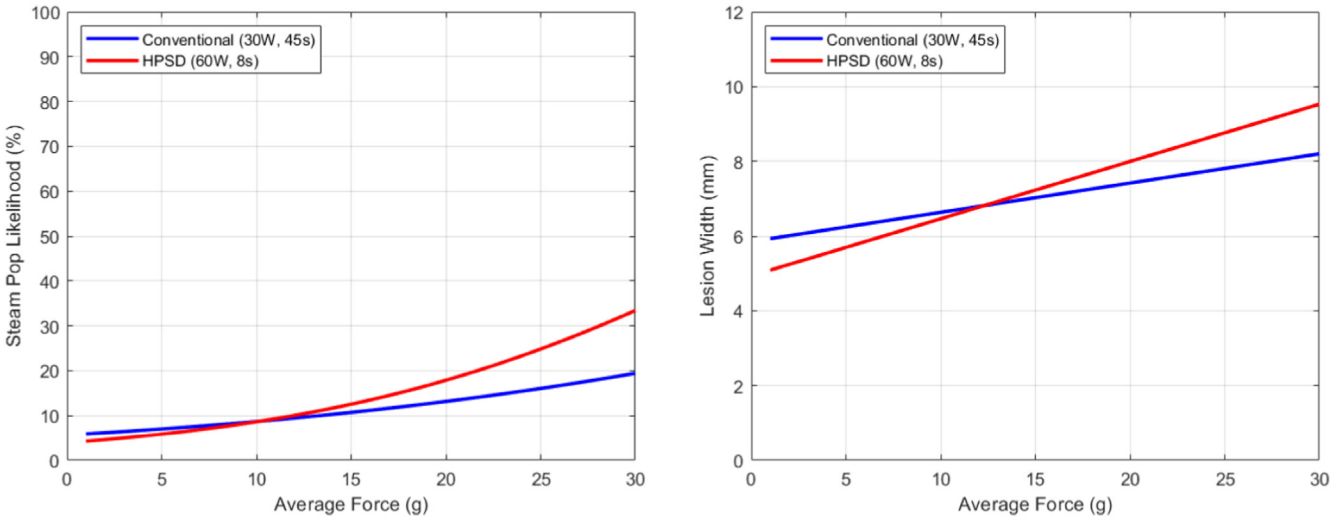

Figure 3 Left: A linear plot illustrating the likelihood of steam pop occurrence vs the mean contact force. Right: Efficacy (lesion width) vs mean contact force. The results were derived from a logistic regression model for binary steam pop responses at conventional power and duration (30 W/45 seconds) and high power and short duration (HPSD) (60 W/8 seconds). The lesion width data are from ventricular lesions in efficacy studies.

from the this intracardiac analysis did not constrict the parameter space any further from the parameter space identified by the thigh study.

The relationships between contact force and steam pop formation and contact force and lesion size were also analyzed. The real-time contact force data were recorded for each ablation, with mean peak-to-peak variability of 9.43 ± 4.47 g. Figure 3 illustrates the likelihood of steam pop occurrence vs the mean contact force and efficacy (lesion width) vs mean contact force. The results were derived from a logistic regression model for binary steam pop responses at conventional power and duration (30 W/45 seconds) and HPSD (60 W/8 seconds). As shown in Figure 3, the impact of contact force on lesion safety and efficacy was more pronounced using HPSD compared with conventional ablation ($P = .038$). Note that the comparison with conventional ablation leveraged historical data from a canine ventricular lesion modeling study (rather than in the same cohort of animals as the HPSD ablations); this study (also with the TactiFlex Ablation Catheter, SE; n = 6 canine, 52 total ablations) assessed ventricular lesion dimensions with respect to target contact force (up to 30 g). At 10 g of contact force, the risk of steam pop formation was similar between HPSD and conventional ablation; however, at 30 g of contact force the likelihood of steam pop formation was >30% with HPSD compared with 20% for conventional ablation. Lesion width was greater with conventional ablation below 10 g of contact force, but when contact force was ≥15 g, HPSD ablation had greater lesion width; the per-gram impact of force on lesion width was significantly greater with HPSD compared with conventional ablation ($P = .001$).

In vivo safety and efficacy study

A second set of in vivo experiments was performed using focal and PVI lesion sets in 14 swine to assess the optimal parameters for lesion formation. Acute PVI was achieved in 13 of 14 veins. RF ablations for successful PVI conducted between 60 and 64 W were executed with durations of 8 to 12 seconds; for power levels between 65 and 70 W, durations of 6 to 10 seconds were employed. Target contact force ranged from 5 to 15 g for all isolations. Figure 4 illustrates the range of RF power, duration, and contact force in which safe (<10% likelihood of steam pop) and effective lesions could be created in the second intracardiac study (n = 14 swine, n = 290 PVI lesions). Logistic regression identified the optimal parameters for RF application were 60 to 70 W with a duration <8 seconds and <15 g contact force (Supplemental Section IV). Under these conditions, atrial focal lesions ranged in width from 4.2 to 12.5 mm and were transmural 80.8% of the time. The percentage of transmural sections and thrombus formation vs the target power, duration, and contact force combinations are shown in Figure 5. Notably, transmural lesion formation decreased with higher powers. Per-animal ablation conditions and descriptive statistics for this study are described in Supplemental Section V.

Discussion

In this study, we sought to systematically define the optimal parameters for HPSD RF application using a novel ablation catheter (TactiFlex SE). There are 3 major findings. First, we found that safe and effective HPSD lesions can be created in a porcine model using this novel, flexible-tipped, force-sensing RF irrigated ablation catheter. Second, these experiments demonstrate that contact force has greater impact on safety and efficacy with HPSD compared with conventional ablation. Finally, these experiments suggest that the optimal lesions for safety and efficacy were created at 60 to 70 W for <8 seconds with <15 g contact force. More specifically, these data in total suggest that RF ablations for successful PVI conducted between 60 and 64 W have an optimal duration of 8 seconds, and for power

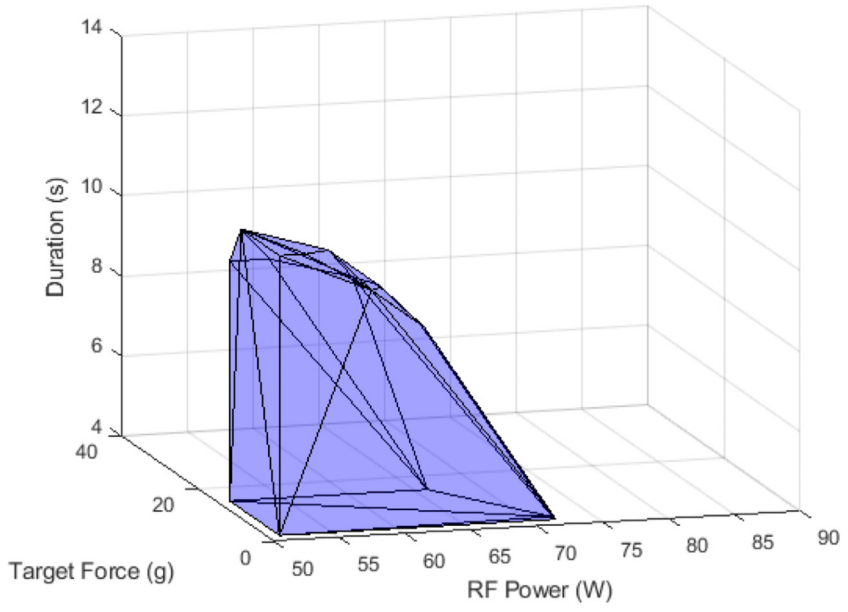

Figure 4 Final 3-dimensional hull of the iteratively reduced design space, informed by low-risk models for steam pop and coagulum likelihood. Steam pop likelihood in the left atrium proved to be the most restrictive; the space illustrates parameter combinations resulting in <10% likelihood for steam pop. RF = radiofrequency.

levels between 65 and 70 W, durations of 6 to 8 seconds are recommended.

Using a systematic approach with a thigh muscle preparation safety study, followed by an in vivo porcine safety analysis focused on steam pop formation, and finally an in vivo safety and efficacy study that incorporated PVI, we sought to define the optimal parameters for HPSD delivery with a novel flexible-tipped, contact force–sensing RF ablation catheter. The optimal HPSD parameters for safety and efficacy with a flexible tip contact force–sensing catheter may be different than nonflexible or other catheters, as the flexible tip may impact stability and other important factors that influence lesion formation. In a preclinical study evaluating an open-irrigated RF catheter using temperature-controlled ablation with a system of 6 thermocouples, Leshem and colleagues[1] identified 90 W × 4 seconds as the best compromise between lesion size and safety parameters (no steam pop or char formation). It is interesting to note

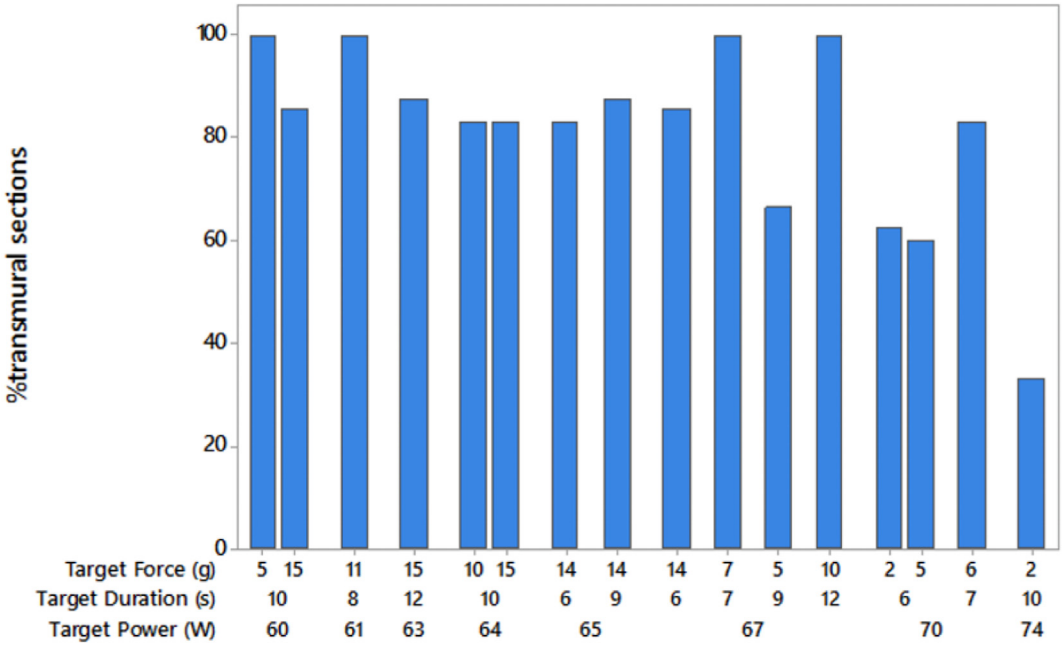

Figure 5 Percentage of transmural sections vs target power, duration, and force combinations (n = 16 swine) from histological analysis of pulmonary veins (3–8 slides per pulmonary vein). Note that transmurality decreases at higher powers.

that the average powers were in the 60 W range. The authors also found that all steam pops occurred when the temperature at the catheter-tissue interface was ≥85°C. When ablation was performed with 90 W for 4 seconds with a temperature limit of 65°C, no steam pops were observed. HPSD was associated with no gaps and complete transmurality compared with 25% gaps and only 71% transmurality with standard ablation.[1]

In this analysis, using power-controlled ablation, we considered a much broader range of power, duration, and varied contact force. Using this broader range and logistic modeling to help narrow optimal parameters, we identified a lower optimal power with longer durations: 60 to 70 W for <8 seconds with <15 g contact force. In contrast to the findings from Leshem and colleagues,[1] we found that higher powers were more likely to result in nontransmural lesions due to the abbreviation of duration required to avoid steam pops. Recent observational studies have also identified higher rates of reconnection with HPSD, especially at the right pulmonary vein carina.[7] It is also worth noting that Leshem and colleagues defined a steam pop as a sudden rise in the impedance accompanied by a temperature drop without catheter movement. In our experiments, we utilized not only impedance and temperature data, but also a Millar catheter and digital stethoscopes.

Another important finding in our analysis is that contact force has greater impact on safety and efficacy with HPSD compared with conventional ablation. Contact force improves the surface area and stability of the electrode-tissue interface and improves thermal energy transfer to the tissue. It is well appreciated that greater contact force leads to greater lesion width, depth, and size.[8–10] The biophysical data from this study show that lesion width was improved with HPSD but only with contact force ≥15 g. The safety data in this study revealed that the likelihood of steam pop formation was much more likely with high contact forces with HPSD compared with conventional ablation. These findings have important implications for catheter ablation procedures utilizing HPSD and very HPSD. In particular, the margin of error for safety events is narrower at high contact forces. HPSD is attractive, in part, because it spares epicardial injury. Prior work from Castrejón-Castrejón and colleagues[11] in the POWER-FAST pilot study revealed 28% evidence of esophageal lesions on endoscopy with 30 W and 10 g of contact force vs no evidence of esophageal lesions with 60 W and 10 g of contact force. However, given the findings of this and other studies,[12] higher contact forces could result in injury to adjacent tissue including the esophagus.

While HPSD has improved the efficiency of AF ablation, its impact on efficacy is less clear. Data on arrhythmia free survival following HPSD vs conventional ablation are mixed. Some studies have suggested improved arrhythmia-free survival. In a study of 197 patients undergoing catheter ablation for paroxysmal atrial fibrillation with the Flexability SE catheter (Abbott), Kottmaier and colleagues[2] found HPSD (70 W × 5–7 seconds) to be associated with greater arrhythmia-free survival compared with conventional ablation (30–40 W × 20–40 seconds): 83% vs 65% were free from atrial fibrillation at 1 year ($P = .013$). In contrast, using a different technique for HPSD, in a much larger cohort of 1333 patients with 3 years of follow-up, Bunch and colleagues[3] found that HPSD (50 W × 2–3 seconds), while associated with shorter fluoroscopy and procedure times, was associated with higher rates of arrhythmia recurrence and need for repeat ablation when compared with conventional ablation (21% vs 30%; $P = .002$). Our preclinical data suggest that at the higher ranges of power application, HPSD may be associated with a lower probability of transmural lesion formation, principally due to the shorter durations required to avoid steam pop.

The results of both the safety analyses that focused on defining the range of HPSD ablation associated with low likelihood of char formation or steam pop formation and the efficacy studies of lesion formation and PVI identified an optimal set of ablation parameters. Delivery of power between 60 to 70 W, duration <8 seconds, and contact force <15 g with the TactiFlex SE catheter led to the best safety and efficacy in this preclinical model. Based on these results, we hypothesize that HPSD with the TactiFlex SE catheter should lead to improved procedural efficiency and may also lead to improved safety and efficacy. This hypothesis will be tested in 2 upcoming clinical trials in patients with paroxysmal and persistent atrial fibrillation (NCT04855890).

Limitations

There are several limitations to keep in mind when considering these results. First, these data were obtained from animal models and cannot serve as perfect proxies for human ablation. Second, the target forces in the ablation scheme were not always achieved to the exact gram. Third, we targeted a lesion depth of 3 mm, which should be appropriate for the majority of left atrial ablation sites. In an analysis of 60 patients undergoing PVI, computed tomography data demonstrated that the average thickness of the left atrial wall was 1.89 ± 0.48 mm.[13] However, thicker tissue thickness can be encountered. For example, as the low lateral ridge can have mean diameters approaching 6 mm,[14] application on either side of the ligament would be expected to yield a transmural lesion. Fourth, while resistive heating would be expected to dominate in HPSD lesions, we cannot discern between the impact of resistive vs conductive heating and tissue injury across different combinations of watts, duration, and contact force. Finally, the findings of this study are not generalizable to other catheters and designs nor other types of irrigation.

Conclusion

Safe and effective HPSD lesions can be created using this novel, flexible-tipped, force-sensing RF irrigated ablation catheter. Contact force has greater impact on safety and

efficacy with HPSD compared with conventional ablation. Optimal lesions for safety and efficacy were created at 60 to 70 W for <8 seconds with <15 g contact force. Chronic studies are ongoing to assess RF parameter refinements and long-term lesion durability using these conditions.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Ethics Statement: The study protocol was approved by the Institutional Animal Care and Use Committee and conforms to the Guide for the Care and Use of Laboratory Animals.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hroo.2023.06.005.

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