Safe and effective delivery of high-power, short-duration radiofrequency ablation lesions with a flexible-tip ablation catheter

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BACKGROUND High-power, short-duration (HPSD) radiofrequency ablation (RFA) may reduce ablation time. Concerns that catheter-mounted thermocouples (TCs) can underestimate tissue temperature, resulting in elevated risk of steam pop formation, potentially limit widespread adoption of HPSD ablation.

OBJECTIVE The purpose of this study was to compare the safety and efficacy of HPSD and low-power, long-duration (LPLD) RFA in the context of pulmonary vein isolation (PVI).

METHODS An open-irrigated ablation catheter with a contact force sensor and a flexible-tip electrode containing a TC at its distal end (TactiFlex™ Ablation Catheter, Sensor Enabled™, Abbott) was used to isolate the left pulmonary veins (PVs) in 12 canines with HPSD RFA (50 W for 10 seconds) and LPLD RFA (30 W for a maximum of 60 seconds). PVI was assessed at 30 minutes and 28 ± 3 days post-ablation. Computed tomographic scans were performed to assess PV stenosis after RFA. Lesions were evaluated with histopathology.

RESULTS A total of 545 ablations were delivered: 252 with LPLD (0 steam pops) and 293 with HPSD RFA (2 steam pops) ($P = .501$). Ablation time required to achieve PVI was >3-fold shorter for HPSD than for LPLD RFA ($P = .001$). All 24 PVs were isolated 30 minutes after ablation, with 12/12 LPLD-ablated and 11/12 HPSD-ablated PVs still isolated at follow-up. Histopathology revealed transmural ablations for HPSD and LPLD RFA. No major adverse events occurred.

CONCLUSION An investigational ablation catheter effectively delivered RFA lesions. Ablation time required to achieve PVI with HPSD with this catheter was >3-fold shorter than with LPLD RFA.

KEYWORDS Atrial fibrillation; High-power; short-duration ablation; Pulmonary vein isolation; Pulmonary vein stenosis; Radiofrequency ablation; Steam pop

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Background

Success of pulmonary vein isolation (PVI) with radiofrequency ablation (RFA) is dependent on delivery of contiguous, transmural lesions.[1–3] Despite numerous advances in RFA technology, including the development of irrigated-tip and contact force–sensing ablation catheters,[4–10] recurrences of AF after PVI remain common.[11,12] High-power, short-duration (HPSD) RFA has the potential to reduce the gaps between ablation lesions that can result in recurrence of AF. Although the overall volumes of HPSD and low-power, long-duration (LPLD) RFA lesions are similar, the ratio of resistive to conductive heating is larger in HPSD

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KEY FINDINGS

- In this study, high-power, short-duration (HPSD) radiofrequency ablation was associated with a >3-fold reduction in the ablation time required to achieve pulmonary vein isolation (PVI).
- Rate of PV isolation was not significantly different for HPSD and low-power, long-duration (LPLD) protocols, both at the time of the ablation procedure and during a repeat invasive electrophysiological study performed 28 ± 3 days after the ablation procedure.
- There was also no significant difference in steam pop formation between the HPSD and LPLD protocols.
- No instances of clinically apparent PV stenosis were observed in this study. Cardiac computed tomographic scans performed on all subjects 28 ± 3 days after the ablation procedure revealed no significant difference in the degree of pulmonary vein narrowing between subjects who underwent ablation with the HPSD and LPLD protocols.

RFA than in LPLD RFA. Consequently, lesions produced with HPSD are wider and shallower than lesions produced with LPLD RFA.[13–16]

Preclinical studies have demonstrated that HPSD RFA can produce transmural ablation lesions in the left atrium and that lesion continuity is improved relative to LPLD.[16–19] In clinical studies, HPSD RFA has been shown to increase acute procedural success, reduce time to PVI, and achieve more durable PVI than LPLD RFA.[17,20–27] Despite the potential advantages of HPSD RFA over LPLD RFA, concerns associated with procedural complications remain. Although some studies demonstrated a lower rate of complications with HPSD compared with LPSD,[17,25] other studies revealed a higher risk of pulmonary vein (PV) stenosis and cardiac tamponade with HPSD.[28,29]

The purpose of this preclinical study was to evaluate the safety and effectiveness of an investigational RFA catheter featuring a flexible-tip electrode and a contact force sensor. The flexible-tip electrode of the investigational device used in the current study was designed to bend slightly when in contact with tissue and to distribute irrigant more evenly around the ablation tip via laser-cut kerfs and distal irrigation ports (Figure 1).[25,30–32] This investigational catheter was used to perform PVI in canines with both HPSD and LPLD protocols. Outcomes of the HPSD and LPLD protocols were compared at the time of the ablation procedure and 28 ± 3 days after the procedure.

Methods

Animal model

Experiments were conducted with 12 adult mongrel canines with normal hearts, each weighing between 30 and 40 kg. The study protocol was reviewed and approved by the Committee for Research Animal Care, in accordance with the American Association of Laboratory Animal Care standards for proper research animal care. In addition, the study protocol adhered to Good Laboratory Practice standards established by the US Food and Drug Administration. Before each procedure, animals were fasted overnight and then brought to the imaging/procedure suite. During each procedure, general anesthesia was induced, and vital signs were monitored continuously.

Electroanatomic mapping, RFA, confirmation of PVI, and assessment of PV stenosis

In this prospective, multioperator study, subjects underwent baseline cardiac computed tomographic (CT) scans with intravenous contrast to define the PV anatomy. Within 7 days of the cardiac CT scan, electroanatomic maps (EAMs) of the atria were generated during sinus rhythm with the EnSite™ Precision mapping system using the TactiFlex™ Ablation Catheter, Sensor Enabled™ (Abbott, Abbott Park, IL) (Figure 1). The small size of the left atrium in canines resulted in restricted catheter access to the right-sided PVs in some subjects. Therefore, this study involved ablation of only the left-sided PVs.

After EAM completion, the same catheter was used to record PV potentials in the left superior PV and left inferior PV. Pacing was then performed from the locations at which PV potentials were measured to confirm capture of the left atrium. The locations at which PV potentials were recorded and pacing was performed were marked on the EAM. Pacing parameters also were recorded.

Left-sided PVs were isolated using either an LPLD RFA protocol (30 W delivered over a maximum of 60 seconds) or an HPSD RFA protocol (50 W delivered over 10 seconds). For LPLD ablation lesions, power delivery was modulated as a function of catheter-based temperature readings (radiofrequency delivery ended if the thermocouple reached 45°C). The duration of individual LPLD ablation lesions (average 38.5 ± 10.6 seconds) was determined by individual operators in response to clinical indicators such as impedance drop and electrogram duration. HPSD ablation lesions involved

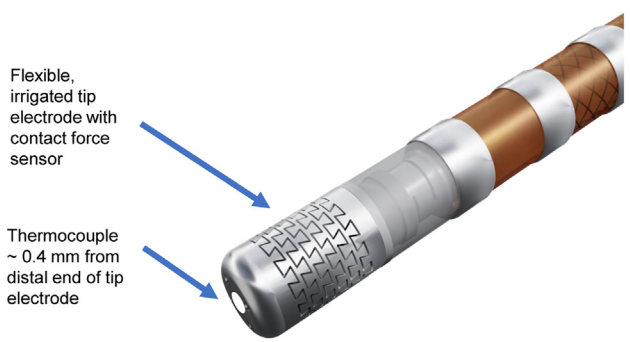

Figure 1 Location of the thermocouple in the investigational catheter used for delivery of high-power, short-duration and low-power, long-duration radiofrequency ablation lesions. Diagram of the experimental catheter utilized in this study is shown. The location of the thermocouple within the tip electrode is represented by a *dot*. The irrigated-tip electrode of this catheter is flexible and is equipped with a contact force sensor.

constant power delivery, without temperature-based modulation. The same irrigation rate (13 mL/min) and contact force targets (5–20*g*) were used for both the HPSD and LPLD RFA protocols. Operators performed PVI according to the HPSD and the LPLD protocols in random order.

Confirmation of PV isolation was performed 30 minutes after RFA in the following manner. Mapping of the left atrium and left-sided PVs was repeated with the ablation catheter, and absence of PV potentials distal to the ablation lines was confirmed. The ablation catheter was then placed at the same locations within the PVs at which pacing was performed before ablation. PV exit block was confirmed by pacing from these saved locations with the same pacing parameters used before ablation. PV entry block was confirmed in the context of both sinus rhythm and pacing from the coronary sinus (with the ablation catheter in the PV). At the conclusion of the ablation procedure, intracardiac echocardiography (ICE) was used to check for pericardial effusion. All subjects were recovered after the ablation procedure.

During recovery, subjects were monitored for clinical evidence of PV stenosis. For each subject, a repeat cardiac CT scan with intravenous contrast was performed 28 ± 3 days after the ablation procedure to measure the PV diameters and to check for pericardial effusion. On the same day as the repeat CT scan, each subject underwent a repeat electrophysiological (EP) study in which PVI was confirmed with the same protocol used during the ablation procedure. A new EAM was generated for each subject, but EAM data from the original EP study were used to inform locations at which pacing was performed to confirm PV entry and exit block. The original EAM data also were used to confirm the location of the original ablation lines and to determine the areas within the PVs at which the catheter would be placed to confirm absence of PV potentials. ICE was used during the second EP study to check for pericardial effusion.

After the invasive cardiac EP studies and cardiac imaging were completed, full necropsy of the study subjects was performed. This included examination of the thoracic cavity, including the heart, mediastinum, lungs, diaphragm, and esophagus. The abdominal cavity, viscera, and brain also were inspected. Hearts were explanted and stained with triphenyl tetrazolium chloride (TTC) before gross inspection of the atria. Representative sections of ablated atrial tissue were fixed in formalin, sectioned, and stained with hematoxylin and eosin as well as Masson trichrome.

Statistical analysis

All comparisons of continuous variables measured for LPLD and HPSD ablations (eg, contact force, power delivery, catheter tip temperature, impedance drop) were performed using 2-sample *t* tests. The Fisher exact test was used for all comparisons of categorical variables (eg, steam pop formation, PVI). The Wilcoxon rank-sum test was used to compare the percentage of PV stenosis after ablation as well as the percentage of ablation lines covered with contiguous ablation lesions for the LPLD and HPSD protocols.

Results

Comparison of RFA parameters measured during delivery of ablations with the HPSD and LPLD protocols

Standard ablation parameters were recorded for all ablations delivered in 12 canines with both the HPSD protocol (N = 293) and the LPLD protocol (N = 252). These parameters included contact force, power delivery, impedance drop, and tissue temperature (measured through catheter tip thermocouple). Contact force and impedance drop did not vary significantly between the LPLD and HPSD protocols (Figure 2). For both the HPSD and the LPLD RFA protocols, the target power was successfully delivered during ablation. Although the absolute difference in the average catheter tip temperature measurements for the HPSD and LPLD protocols was small (0.77°C), this difference was statistically significant.

Positional stability of the ablation catheter tip was measured for all RFA lesions delivered in this study. Stable catheter tip position was defined to involve movement ≤2 mm from the start position during RFA. If the catheter tip position was found to be unstable, ablation was stopped and the catheter was repositioned before ablation was resumed. Only 4 of the 545 ablations (0.7%) delivered in this study were stopped prematurely due to catheter tip movements >2 mm.

Measurement of ablation time required to achieve PVI with the HPSD and LPLD RFA protocols

The total ablation time required to achieve PVI was measured for each subject. Average ablation time was longer for LPLD than for HPSD (813 ± 460 seconds vs 242 ± 105 seconds, respectively; $P = .001$). A comparison of total ablation times for the HPSD and the LPLD protocols is shown in Figure 3.

Rate of successful PVI with the HPSD and LPLD RFA protocols

PVI was assessed both during the ablation procedure and during a separate EP study performed 28 ± 3 days after the ablation procedure. Rate of PV isolation was calculated for both HPSD and LPLD RFA protocols at both time points. All veins ablated with both techniques were found to be isolated during the initial ablation procedure (Table 1). Repeat check of PV isolation performed 28 ± 3 days after the ablation revealed that 12 of 12 PVs ablated with the LPLD protocol remained isolated vs 11 of 12 PVs ablated with the HPSD protocol that remained isolated ($P = 1$).

Comparison of rate of steam pop formation with the HPSD and LPLD RFA protocols

All steam pops that occurred during ablation with both the HPSD and LPLD RFA protocols were recorded. The rates of steam pop formation for both ablation protocols were compared. No steam pops were observed for ablations delivered with the LPLD protocol. Of the 293 ablations delivered

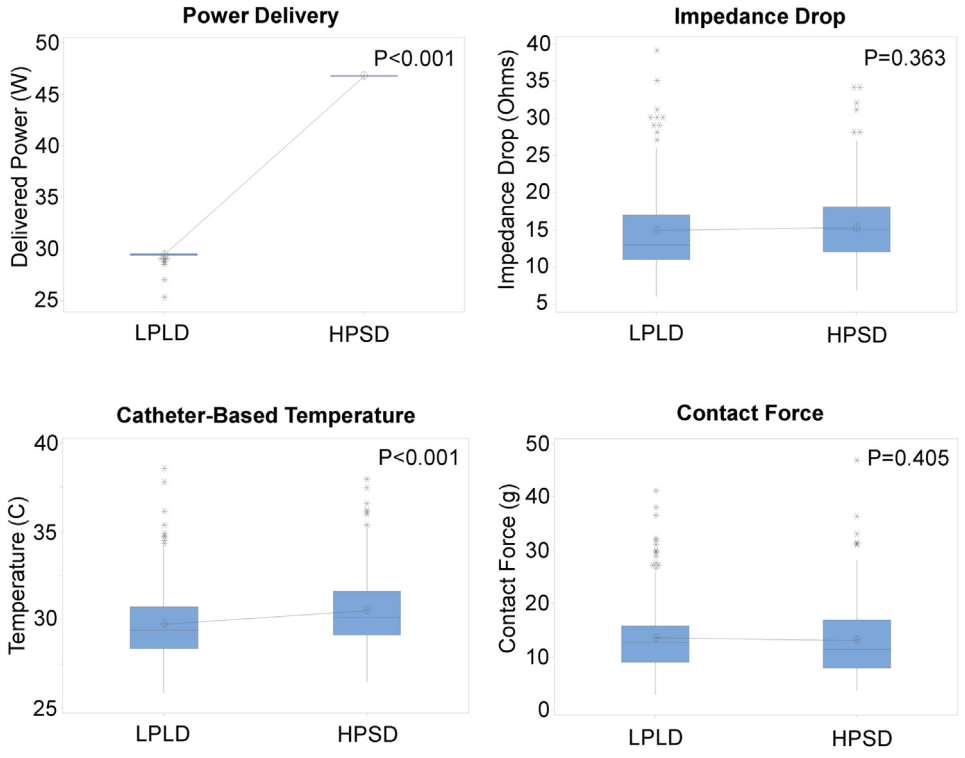

Figure 2 Comparison of measured ablation parameters for high-power, short-duration (HPSD) and low-power, long-duration (LPLD) radiofrequency ablation lesions. Box plots comparing ablation parameters (power delivery **[top left],** impedance drop **[top right],** catheter-based temperature **[bottom left],** and contact force **[bottom right]**) measured during HPSD and standard radiofrequency ablation lesions are shown. *Upper* and *lower boundaries* of the box plots represent middle quartiles. *Horizontal line* within the box represents the median value. *Diagonal lines* connect the mean values, which are represented as *circles* within the boxes. Boundaries of the *vertical line* represent 1 SD. Outliers are represented as *asterisks.*

with the HPSD protocol, 2 (0.7%) resulted in steam pops (Supplemental Figure 1). The rates of steam pop formation were not statistically different between HPSD (2/293; 95% confidence interval [CI] 0.000–0.015) and LPLD (0/252; 95% CI 0.001–0.024) RFA protocols ($P = .501$).

Outcomes after RFA with the HPSD and LPLD RFA protocols

Major adverse events (death, pericardial effusion, pulmonary edema) during the ablation procedure and the first 28 days after the ablation procedure are listed in Table 2.

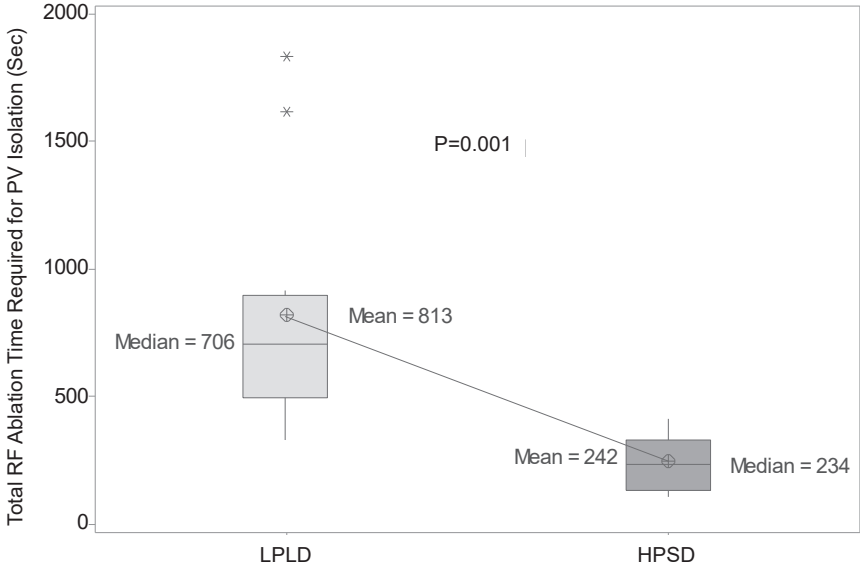

Figure 3 Radiofrequency (RF) ablation time required to achieve pulmonary vein (PV) isolation with high-power, short-duration (HPSD) and low-power, long-duration (LPLD) protocols. Box plots comparing the RF ablation time required to achieve PV isolation with HPSD and LPLD RFA are shown. *Upper* and *lower boundaries* of the box plots represent middle quartiles. *Horizontal line* within the box represents the median value. *Diagonal line* connects the mean values, which are represented as *circles* within the boxes. Boundaries of the *vertical lines* represent 1 SD. Outliers are represented as *asterisks* beyond the end of the vertical lines.

Table 1 Rate of PVI with HPSD and LPLD RFA protocols

	LPLD RFA	HPSD RFA	*P* value
30 min after ablation	12/12	12/12	1
28 ± 3 d after ablation	12/12	11/12	1

Values are given as PVs ablated/isolated unless otherwise indicated.
HPSD = high-power, short-duration; LPLD = low-power, long-duration; PVI = pulmonary vein isolation; RFA = radiofrequency ablation.

Intraprocedural ICE during the initial ablation procedure did not reveal evidence of pericardial effusion in any of the subjects. During recovery, none of the subjects developed clinical signs of heart failure, including pulmonary edema. Follow-up CT scans performed 28 ± 3 days after the ablation procedure did not reveal evidence of pericardial effusion in any of the subjects. Gross pathologic analysis performed at the termination of the study did not reveal any evidence of cardiac, esophageal, or lung injury.

Assessment of PV diameter after ablation with the HPSD and LPLD RFA protocols

For each study subject, the diameters of the PVs were measured with CT scans performed within 7 days before the ablation and again 28 ± 3 days after ablation. These measurements were compared (Figure 4A). The degree of PV stenosis was measured (Figure 4B). None of the subjects presented with PV stenosis >70% after ablation. Average PV stenosis was <30% and was not significantly different between the HPSD and LPLD RFA protocols (Figure 4).

Necropsy of study subjects

Pathologic examination revealed no clinically significant adverse effects associated with ablation performed with the investigational catheter. Specifically, there was no evidence of pericardial effusion or atrial-esophageal fistula. In addition, gross and microscopic evaluation of the phrenic nerve, lungs, and esophagus revealed no evidence of significant tissue damage.

Histopathologic analysis of ablated tissue

Inspection of the endocardial surface of TTC-stained hearts revealed evidence of healing ablation lesions at the ostia of all treated PV s (left inferior PV, left superior PV). Gross examination of the epicardial surface did not reveal any obvious gaps between ablation lesions in each treated PV. A representative example is shown in Figure 5A. There was no observed loss of endocardial or myocardial continuity. In addition, there was no evidence of charring or other injury at any of the inspected sites in the left atrium.

The TTC-stained endocardium at the ostium of each ablated PV was inspected to determine whether gaps between lesions were present. For each ablation protocol (HPSD, LPLD), the average percentage of ablation coverage was calculated. This analysis revealed that the average ablation coverage was 97.7% ± 6.1% for LPLD and 98.3% ± 3.4% for HPSD ($P = .590$).

Table 2 Subject outcomes after RFA procedures

		LPLD RFA	HPSD RFA	*P* value
Mortality	Intraprocedural	0/6	0/6	1
	28 ± 3 d after ablation	0/6	0/6	1
Pericardial effusion	Intraprocedural	0/6	0/6	1
	28 ± 3 d after ablation	0/6	0/6	1
Pulmonary edema	Intraprocedural	0/6	0/6	1
	28 ± 3 d after ablation	0/6	0/6	1

Abbreviations as in Table 1.

Formalin-fixed sections were prepared from each ablated PV. These sections were oriented perpendicular to the endocardial surface to visualize the depth of the ablation lesions. Staining of each section with hematoxylin and eosin as well as Masson trichrome revealed the presence of contiguous, transmural ablation lesions in all sections analyzed (Figure 5B). Stained sections did not reveal any other evidence of endocardial injury, consistent with the gross pathologic examination.

Discussion

This preclinical study of an investigational ablation catheter, equipped with a contact force sensor within a flexible-tip electrode designed to enhance irrigation, produced the following key findings. No untoward outcomes (eg, mortality, pericardial effusion/tamponade, esophageal injury, clinically significant PV stenosis) were observed in subjects who underwent either HPSD or LPLD RFA. Ablation time required to achieve PVI was >3-fold shorter for HPSD. There was no significant difference between HSPD and LPLD with respect to the rate of PVI at the time of either the initial ablation procedure or at a postablation EP study performed 28 ± 3 days after ablation.

The goal of the HPSD RFA protocol used in this study (50 W over 10 seconds with constant power delivery) was to generate transmural lesions in the left atrium. This HPSD RFA protocol was informed by previous studies of HPSD RFA. One preclinical study demonstrated that 50 W of RFA delivered for 7 seconds created ablation lesions 4 mm deep, potentially deep enough to be transmural in the thin-walled left atrium.[33] Other studies demonstrated that HPSD RFA with a contact force–sensing ablation catheter and power delivery of 50 W guided by lesion size index or ablation index was safe and effective, with an average ablation lesion time of approximately 11 seconds.[34,35] We avoided higher power delivery (>50 W) in this protocol because previous studies have described elevated rates of steam pop formation with power delivery >70 W and ablation times >5 seconds.[16] In addition, higher power settings have been shown to generate larger lesion volumes, which may not be necessary in the left atrium.[18]

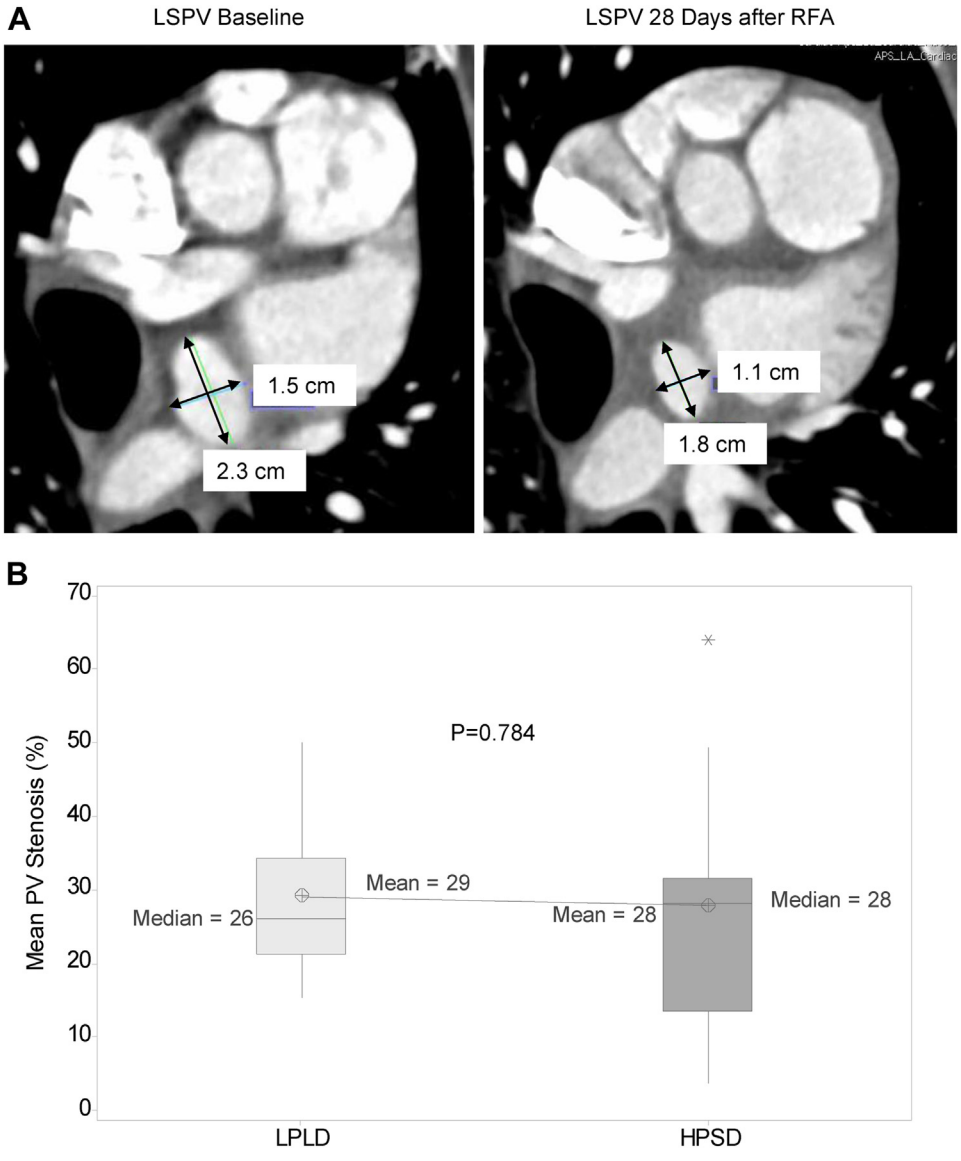

Figure 4 Pulmonary vein (PV) ostium measurements before and after high-power, short-duration (HPSD) and low-power, long-duration (LPLD) radiofrequency ablation (RFA). **A:** Representative computed tomographic (CT) angiograms of the left atrium performed at baseline (within 7 days before HPSD RFA) and 28 days after HPSD RFA. Dimensions of the left superior pulmonary vein (LSPV) ostium before and after ablation are marked. The anterior and posterior walls of the heart are located at the top and bottom of each panel, respectively. The left side of the heart is on the right side of each panel. **B:** Bar graph showing the average reduction in PV diameter observed after RFA, as measured with CT angiography. *Lines* represent 1 SD. Percentage reduction was compared for the HPSD and LPLD RFA protocols.

With the investigational catheter described in the current study, mean power delivery matched the target power delivery for both the HPSD and the LPLD protocols. A small but statistically significant increase in average catheter temperature measurement was observed in HPSD RFA. Two steam pops were observed with the HPSD RFA protocol (0.7% of lesions delivered) compared with 0 steam pops for the LPLD RFA protocol. This small difference was not statistically significant and the confidence intervals overlapped. For both steam pops observed in the current study, an increase in catheter-measured temperature was detected before the event (Supplemental Figure 1). Because the study was designed to characterize the safety of the investigational device under worst-case use conditions, power delivery was not reduced or interrupted in response to the observed temperature increases or other clinical indicators of impending adverse events during HPSD RFA. It is possible these steam pops could have been avoided if power delivery were modulated in response to clinical observations, as would be the case in standard clinical use. Previous clinical studies have demonstrated that HPSD RFA can be safe and effective when power modulation is used.[20,36]

In the current study, no major adverse events were observed after RFA. Necropsy revealed no evidence of significant damage to the heart or the structures adjoining the heart, including the esophagus and the lungs, in all study

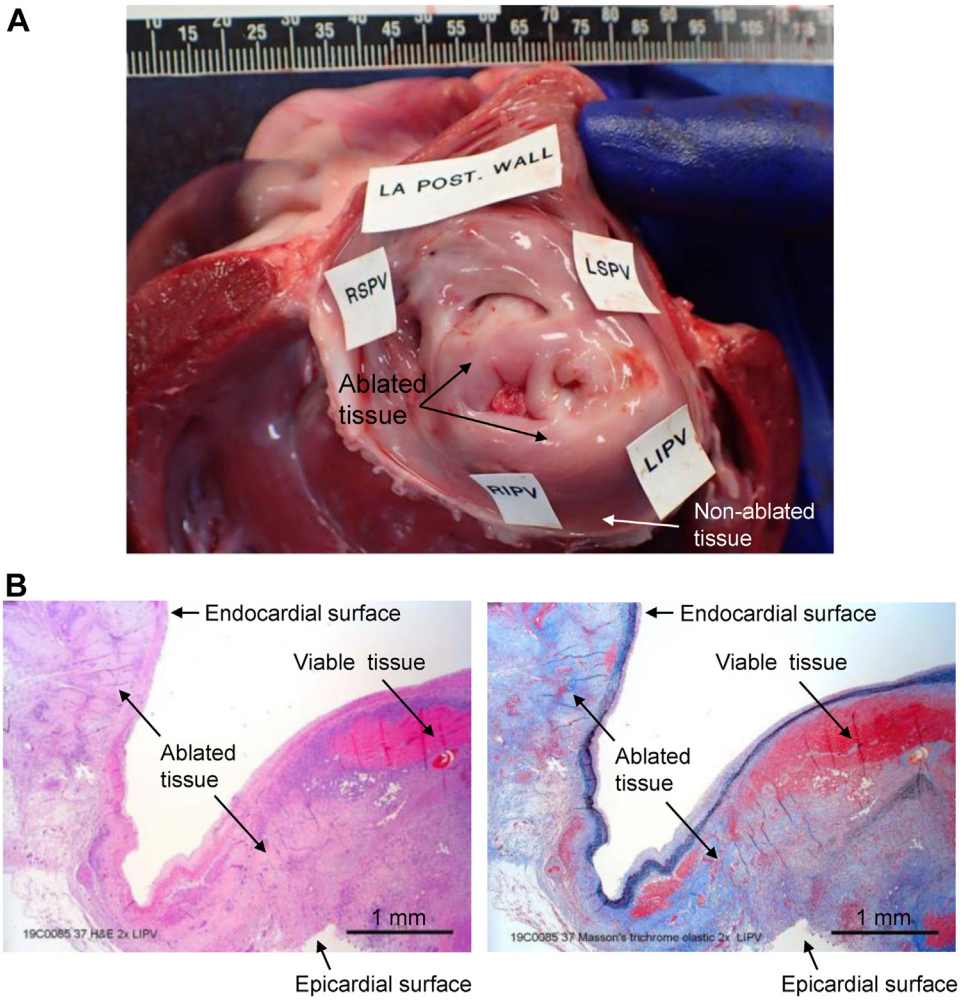

Figure 5 Histopathologic analysis of the left atrium performed at the end of the postablation recovery period. **A:** Representative gross pathologic analysis of the endocardial surface of the left atrium stained with triphenyl tetrazolium chloride. This view reveals the locations of the left atrial posterior wall (LA POST WALL), as well as the locations of the right superior pulmonary vein (RSPV), right inferior pulmonary vein (RIPV), left superior pulmonary vein (LSPV), and left inferior pulmonary vein (LIPV). Ablated areas appear pale compared with nonablated areas. **B:** Histopathologic staining of a representative section of ablated tissue taken from the ostium of the LIPV. This section was taken perpendicular to the long axis of the pulmonary vein. Staining performed with hematoxylin and eosin **(left)** and Masson trichrome **(right)**. Endocardial and epicardial surfaces are labeled. Areas of ablation reveal evidence of necrosis and fibrosis with both hematoxylin and eosin and Masson trichrome staining (labeled in each panel). Areas of scar deposition are stained *blue.* Ablated areas extend from the endocardial surface to the epicardial surface. An area of viable myocardium adjacent to the ablated area is visible in both panels.

subjects. Gross pathology also revealed no evidence of cerebrovascular infarcts. Histopathologic analysis confirmed the presence of transmural lesions at the ablated sites, without any evidence of disruption of the endocardial surface in any study subjects. TTC staining revealed that ablation coverage on the endocardial surface was not significantly different for HPSD and LPLD RFA protocols (approximately 98% for both). Although no large gaps between lesions were observed, it is possible that minute gaps between lesions were responsible for the single vein reconnection observed in this study.

None of the study subjects presented with pulmonary edema or other clinical evidence of PV stenosis after RFA. In addition, cardiac CT did not reveal PV stenosis >70% after either HPSD or LPLD RFA. The degree of PV narrowing, measured 28 ± 3 days after ablation, was not significantly different between HPSD and LPLD RFA.

The reduction in ablation time associated with HPSD vs LPLD was larger than described in some previous studies of HPSD RFA.[17,21,23–26] In the current study, the shorter RFA time for the HPSD RFA did not come at the cost of reduced PVI durability. There was no significant difference in success of PVI between HPSD and LPLD RFA, assessed at 30 minutes and 28 ± 3 days after ablation.

Study limitations

The small sample size of this study may limit our ability to detect differences in rare events such as steam pops. Further study is required to investigate rare complications associated with HPSD RFA. In addition, the data are for a flexible-tip ablation catheter equipped with a contact force sensor. It is possible results would be different with other catheters.

Conclusion

In this preclinical study, an investigational catheter equipped with an advanced irrigation design and a contact force sensor was used to successfully achieve PV isolation with HPSD and LPLD RFA protocols. The HPSD RFA protocol used in this study involved fixed ablation time and power delivery. Time of ablation was significantly lower for HPSD than for LPLD RFA. Recheck of the PVs 28 ± 3 days after ablation revealed no significant difference between HPSD and LPLD protocols with respect to the durability of PV isolation. No untoward events were reported (pericardial effusion, clinical heart failure, mortality) for either HPSD or LPLD RFA. CT scan revealed no evidence of PV stenosis >70%.

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

Ethics Statement: The study protocol was reviewed and approved by the Committee for Research Animal Care, in accordance with the American Association of Laboratory Animal Care standards for proper research animal care. In addition, the study protocol adhered to Good Laboratory Practice standards established by the US Food and Drug Administration.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hroo.2022.10.009.

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