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Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions

The QDOT-FAST Trial

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ABSTRACT

OBJECTIVES This study sought to evaluate the safety and short-term performance of a novel catheter for very high power–short duration (vHPSD) ablation in the treatment of paroxysmal atrial fibrillation.

BACKGROUND The vHPSD catheter is a novel contact force–sensing catheter optimized for temperature-controlled radiofrequency ablation with microelectrodes and 6 thermocouples for real-time temperature monitoring; the associated vHPSD algorithm modulates power to maintain target temperature during 90 W, 4 s lesions.

METHODS QDOT-FAST (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMART-TOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation) is a prospective, multicenter, single-arm study enrolling patients with symptomatic paroxysmal atrial fibrillation indicated for catheter-based pulmonary vein isolation. Primary endpoints were short-term effectiveness (confirmation of entrance block in all targeted pulmonary veins after adenosine/isoproterenol challenge) and short-term safety (primary adverse events). Participants were screened for silent cerebral lesions by magnetic resonance imaging. Patients were followed for 3 months post-ablation.

RESULTS A total of 52 patients underwent ablation and completed follow-up. Pulmonary vein isolation was achieved in all patients using the study catheter alone, with total procedure and fluoroscopy times of 105.2 ± 24.7 min and 6.6 ± 8.2 min, respectively. Most patients (n = 49; 94.2%) were in sinus rhythm at 3 months. Two primary adverse events were reported: 1 pseudoaneurysm; and 1 asymptomatic thromboembolism. There were no deaths, stroke, atrioesophageal fistula, pulmonary vein stenosis, or unanticipated adverse device effects. Six patients had identified silent cerebral lesions—all classified as asymptomatic without clinical or neurologic deficits.

CONCLUSIONS This first-in-human study of a novel catheter with optimized temperature control demonstrated the clinical feasibility and safety of vHPSD ablation. Procedure and fluoroscopy times were substantially lower than historical standard ablation with point-by-point catheters. (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation [QDOT-FAST]; NCT03459196) (J Am Coll Cardiol EP 2019;5:778–86) © 2019 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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Electrical isolation of the pulmonary veins (PV) via radiofrequency catheter ablation is an effective and widely available treatment for paroxysmal atrial fibrillation (PAF) (1). Over the past decade, catheter development has focused on optimizing efficiency and safety, with the development of contact force (CF) catheters representing a significant milestone. CF catheters have been linked to improved long-term outcomes compared with traditional non-CF catheters (2–6). The benefits of CF sensing were demonstrated in both the SMART AF (THERMOCOOL SMARTTOUCH Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation) (4) and the TOCCASTAR (TactiCath Contact Force Ablation Catheter Study for Atrial Fibrillation) (2) studies. In addition, CF stability was an important predictor of reduced arrhythmia recurrence (4,7). Enhanced catheter irrigation technology, with the aim of providing uniform cooling with less fluid delivery, has further improved procedural efficiency, as demonstrated in the SMART SF (SMART SF Radiofrequency Ablation Safety Study) (8).

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Although point-by-point catheter ablation allows for flexible lesion sets for both pulmonary vein isolation (PVI) and additional extra-PV ablations, creation of multiple individual lesions (each between 15 and 45 s) can drive long procedure times. There is an ongoing need to improve procedural efficiencies, including shortening overall procedure and fluoroscopy times. A very high power-short duration (vHPSD) strategy of radiofrequency ablation aims to minimize conductive heating and increase resistive heating in order to deliver targeted heating to the atrial wall, while reducing the risk of collateral tissue damage (9–11). Clinical application of a version of this strategy using standard ablation catheters and power limited to 50 W has been described in case series, with favorable safety and improvements in efficiency (12,13).

The vHPSD catheter, previously described in detail (9,10), is a novel CF catheter optimized for temperature-controlled ablation with microelectrodes and 6 thermocouples for real-time temperature monitoring during ablation (**Figure 1A**). The associated vHPSD algorithm modulates power to maintain target temperature during these vHPSD lesions (90 W, 4 s) (**Figure 1B**). In the conventional ablation mode with standard power, temperature-controlled ablation is enabled whereby the algorithm adjusted the irrigation rate based on temperature, to both cool the catheter tip adequately and retain temperature sensitivity. In preclinical models, vHPSD ablation with this novel catheter has improved atrial linear lesion contiguity, transmurality, and durability and has substantially reduced radiofrequency ablation times, but with a safety profile similar to those of standard irrigated radiofrequency ablation catheters (9,10,14).

In this study (QDOT-FAST [Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation]), we evaluated the safety and short-term performance of the catheter used in combination with a multichannel radiofrequency generator with a vHPSD ablation mode to treat PAF.

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation
CF = contact force
MRI = magnetic resonance imaging
PAE = primary adverse event
PAF = paroxysmal atrial fibrillation
PV = pulmonary vein
PVI = pulmonary vein isolation
SCL = silent cerebral lesion
vHPSD = very high power-short duration

METHODS

The study was conducted in accordance with the Declaration of Helsinki and was approved and reviewed by ethics committees at all participating sites and by local health authorities in the participating countries. Each patient provided written informed consent prior to treatment. Local country privacy laws were followed.

(see the comprehensive list in the Online Appendix). Dr. Grimaldi has a patent agreement with Biosense Webster (Johnson and Johnson) that is not related to the submitted work. Dr. De Potter reports nonfinancial support from Johnson and Johnson during the conduct of the study. Dr. Martinek has received personal fees unrelated to the submitted work from Biosense Webster (Johnson and Johnson), Abbott Medical, Medtronic, and Boston Scientific; has served as a speaker, advisory board member, and proctor for Biosense Webster (Johnson and Johnson), Abbott Medical, and Boston Scientific; and has served as a speaker and proctor for Medtronic. Dr. Knecht has received grants and personal fees unrelated to the submitted work from Biosense Webster (Johnson and Johnson), Medtronic, Abbott Medical, and Boston Scientific. Dr. Pürerfellner has received honoraria for consulting and speaking during the conduct of the study and unrelated to the submitted work from Biosense Webster (Johnson and Johnson). All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.
All authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Clinical Electrophysiology* author instructions page.

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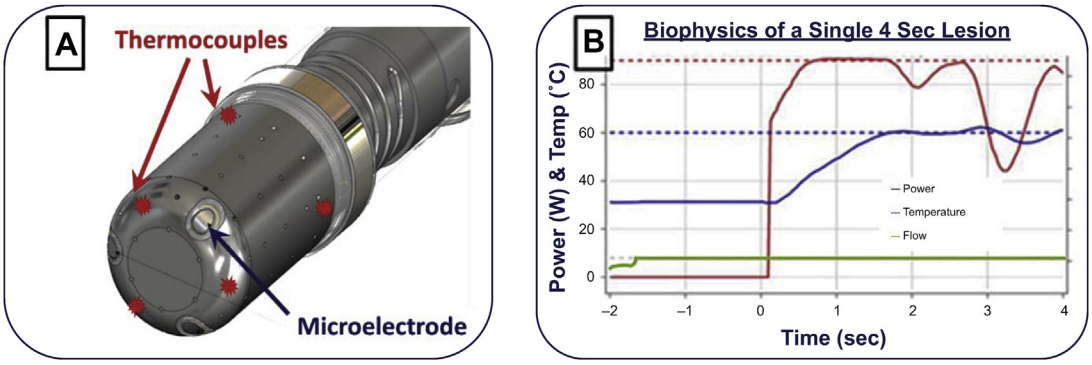
FIGURE 1 The vHPSD Catheter



(A) The very high power–short duration (vHPSD) catheter tip is shown highlighting the microelectrodes and 6 thermocouples. **(B)** The biophysical parameters of an example ablation lesion is shown. This includes a 2-s pre-cooling phase, followed by a 4-s vHPSD ablation lesion. Note the power modulation that is particularly striking in the last 1.5 s of energy delivery to maintain the target temperature of 60°C.

STUDY DESIGN. QDOT-FAST was a first-in-human, prospective, multicenter, single-arm, clinical study of the QDOT Micro catheter (Biosense Webster, Inc., Irvine, California) conducted in 4 European countries (Austria, Belgium, Czech Republic, and Italy). Follow-up was performed at 7 days, 1 month (if applicable for newly detected silent cerebral lesion [SCL]), and 3 months after the ablation procedure.

STUDY POPULATION. Eligible patients were aged 18 years or older, were diagnosed with symptomatic PAF (defined as atrial fibrillation [AF] that terminates spontaneously or with intervention within 7 days of onset), were candidates for PVI, and were able to comply with follow-up clinic visits. Exclusion criteria included previous surgical or catheter ablation for AF; previous diagnosis of long-standing persistent AF, continuous AF of more than 7 days' duration, or AF for more than 48 h terminated by cardioversion; documented left atrial thrombus at pre-procedure imaging; and uncontrolled New York Heart Association functional class III or IV heart failure.

ABLATION PROCEDURE. After transseptal puncture, electroanatomic mapping was performed using the CARTO 3 System (Biosense Webster, Inc.) with either a Lasso or Pentaray catheter (Biosense Webster, Inc.). The primary ablation mode for PVI was vHPSD ablation: 90 W, 4 s; irrigation at 8 ml/min; recommended CF working range 5 to 30g. The vHPSD algorithm rapidly cycled power based on the hottest surface thermocouple (cutoff at 65° to 70°C). Irrigation flow rate delays of a minimum of 2 s and 4 s were set before and after every radiofrequency application, respectively. Touch-up with a "standard" power titration mode, with temperature control ablation and a power limit of 50 W, was allowed to achieve PVI if deemed necessary by the investigators. PVI was confirmed via entrance block with either a Lasso or Pentaray catheter, followed by a 20-min waiting period and/or adenosine or isoproterenol challenge to rule out dormant conduction. Additional touch-up applications were permitted if PV reconnections were observed short-term. Cavotricuspid isthmus ablation was allowed in the event of typical atrial flutter or atrial tachycardia.

Uninterrupted systemic anticoagulation was recommended for at least 3 weeks pre-ablation and was strongly recommended for 2 months following ablation. Intraprocedural heparin was administered to target an activated clotting time of 300 to 400 s. Esophageal temperature monitoring was employed in 51 patients, intracardiac echocardiography in 14, and barium contrast in 5.

STUDY OUTCOMES. The primary endpoints were short-term effectiveness and safety. Short-term effectiveness was assessed by confirmation of entrance block in all targeted PV after adenosine/isoproterenol challenge. The use of a nonstudy catheter for PVI was considered an effectiveness failure. Short-term safety was evaluated based on the incidence of early onset (within 7 days of the procedure) primary adverse events (PAE). These included atrioesophageal fistula, cardiac tamponade or

TABLE 1 Patient Characteristics and Medical History (N = 54)

Age, yrs	62.0 ± 12.01
Male	36 (66.7)
CHA_2DS_2-VASc	2.0 ± 1.47
AF duration, months	28.5 (9.5-80.5)
Medical history	
Atrial flutter	6 (11.1)
Hypertension	34 (63.0)
Diabetes	5 (9.3)
Coronary disease	4 (7.4)
Prior thromboembolic events	4 (7.4)
Congestive heart failure	10 (18.5)
NYHA functional class	
I	3 (30.0)
II	7 (70.0)
Failed antiarrhythmic drug class	50 (92.6)
Failed medications, n	1.7 ± 0.8
Left ventricular ejection fraction, %	60.8 ± 5.0
Left atrial dimension, mm	39.3 ± 5.16

Values are mean ± SD, n (%), or median (interquartile range).

AF = atrial fibrillation; CHA_2DS_2-VASc = Congestive Heart Failure, Hypertension, Age ≥75 Years, Diabetes Mellitus, Prior Stroke or Transient Ischemic Attack or Thromboembolism, Vascular Disease, Age 65 to 74 Years, Sex; NYHA = New York Heart Association.

perforation, death, major vascular access complication or bleeding, myocardial infarction, phrenic nerve paralysis, PV stenosis, stroke or cerebrovascular accident, thromboembolism, or transient ischemic attack. Device- or procedure-related death, PV stenosis, and atrioesophageal fistula that occurred more than 7 days post-procedure were also included as PAE. Secondary safety endpoints included the incidences of serious adverse device effects (defined as serious adverse events that were either device- or procedure-related); pre- and post-ablation asymptomatic and symptomatic cerebral emboli as determined by cardiac magnetic resonance (MRI); and new or worsening neurologic deficits.

The study actively screened for post-procedural cerebral lesions with MRI within 72 h pre-ablation and 72 h post-ablation. At follow-up, patients were required to undergo an MRI examination if cerebral ischemic lesions were identified in a prior evaluation or if the patient experienced neurologic symptoms. If cerebral lesions were detected, follow-up was performed 1 month later, including MRI and neurologic assessments (National Institutes of Health Stroke Scale, Montreal Cognitive Assessment, and Modified Rankin Scale). If neurologic symptoms or cerebral ischemic lesions were identified at a prior evaluation, subjects were required to undergo MRI and neurological assessments at the next evaluation.

Antiarrhythmic drug management following the AF ablation procedure was at the discretion of the investigator. At 3-month follow-up, rhythm assessment was collected per standard of care electrocardiogram data.

STATISTICAL METHODS. As this was a feasibility study, there was no statistical power calculation and no hypothesis generated. A cohort of 52 treated patients was deemed sufficient to characterize safety and procedural outcomes. Only descriptive summary statistics were analyzed.

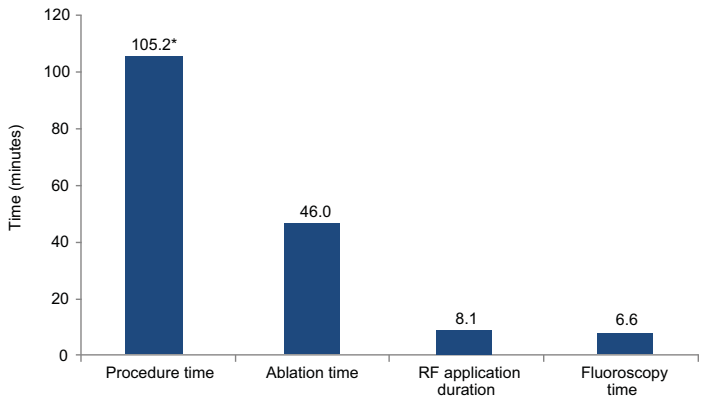
RESULTS

PATIENT DISPOSITION AND CHARACTERISTICS. Between April 17, 2018, and June 20, 2018, a total of 54 patients were enrolled at 7 sites (10 operators), with 52 eligible patients included for safety and effectiveness analyses. One enrolled patient had an implanted pacemaker and, thus, did not meet the eligibility criteria, and 1 patient withdrew consent before the ablation procedure. All 52 patients underwent post-ablation neurologic assessments, and all patients completed the 3-month follow-up period.

Baseline characteristics and medical history are summarized in Table 1. Consistent with most PAF populations, the age of enrolled patients was relatively young (age 62.0 ± 12.0 years), approximately two-thirds were men, the overall rate of comorbidities was moderate (63.0% hypertension; 18.5% congestive heart failure), and the anteroposterior left atrial diameter was moderately enlarged (39.3 ± 5.2 mm).

AF ABLATION PROCEDURE. Of the 52 participants who underwent ablation, PVI was performed in all; only 1 patient received additional ablation—roof line and a line between the left and right inferior PV. None required a second ablation for PAF during the follow-up interval. The total number of radiofrequency applications was 108.3 ± 42.5, with CF 16.9 ± 6.7*g* (minimum 8.1*g* and maximum 36*g*) and power 85.4 ± 6.7 W. As shown in Figure 2, the total procedure time (defined as the time of first puncture until the time of last catheter removed), including a 20-min waiting time and the adenosine or isoproterenol challenge, was 105.2 ± 24.7 min (range 68.0 to 177.0 min). Of this total procedure time, the mapping time was 9.5 ± 5.3 min, fluoroscopy time was 6.6 ± 8.24 min, total PV ablation time was 44.3 ± 22.4 min, total ablation time (from the time of the first radiofrequency application to the time of the

FIGURE 2 Procedural Parameters in the QDOT-FAST Study



Key procedural parameters are shown for both the first-in-man QDOT-FAST (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation) trial, as well as previous multicenter studies: the THERMOCOOL AF (THERMOCOOL SMARTTOUCH Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation) trial, which investigated a saline-irrigated RF ablation catheter (3); the SMART AF (THERMOCOOL SMARTTOUCH Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation) trial, which investigated a saline-irrigated force-sensing ablation catheter (4); and the SMART-SF (SMART SF Radiofrequency Ablation Safety Study) trial, which investigated a force-sensing ablation catheter with enhanced saline irrigation (8). *Note: Procedure time included 20-min waiting period. RF = radiofrequency.

last radiofrequency application) was 46.0 ± 21.3 min, and left atrial dwell time (time from catheter insertion in the left atrium until removal from the left atrium) was 81.7 ± 20.2 min. For the 50 patients for whom data were collected, the volume of fluid delivered by the ablation catheter was 382.4 ± 299.1 ml. Compared with previous studies using CF and non-CF catheters, the QDOT-FAST study demonstrated substantially shorter total procedure, ablation, fluoroscopy, and radiofrequency application times, and less irrigation fluid load (**Central Illustration**).

EFFECTIVENESS. The primary effectiveness endpoint (PVI confirmed after adenosine or isoproterenol challenge) was achieved using the study catheter in all patients. Of note, in 78.8% of cases (41 of 52), PVI was achieved using the vHPSD mode only. In 26.9% of patients (14 of 52) and 5.0% of veins (22 of 444), PV reconnection after adenosine/isoproterenol prompted additional lesions, the majority posteriorly (**Table 2**). The original lesions were created with a combination of vHPSD and standard ablation in 5 veins and with vHPSD ablation only in the other 17 veins showing reconnection. There were no applications placed with a nonstudy catheter. At the 3-month follow-up visit, 49 patients (94.2%) were in sinus rhythm, whereas 2 patients were in AF and 1 was in atrial flutter.

SAFETY. In 52 patients, 2 PAE (3.8%) were reported: 1 femoral pseudoaneurysm (also classified as a serious adverse device effect and successfully treated by thrombin injection); and 1 asymptomatic thromboembolism (2 new micro emboli; present in MRI at discharge and reconfirmed at 1 and 5 months post-procedure). There were no deaths, strokes, atrioesophageal fistulas, PV stenoses, or unanticipated adverse device effects (**Table 3**). An additional serious adverse device effect (esophageal ulcer hemorrhage) was observed via post-procedural endoscopy at day 1 and healed with medication.

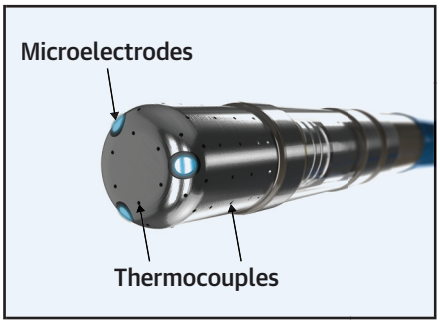
Of 51 patients who had an MRI post-ablation, SCL were found in 6 patients (1 patient who was classified as having a PAE of thromboembolism had 2 new micro emboli; the remainder exhibited only 1 new micro emboli). Four of these patients were on uninterrupted anticoagulation for at least 3 weeks before ablation, 1 patient was on warfarin that was interrupted the day before the procedure, and 1 was not using anticoagulation therapy. All lesions were classified as asymptomatic cerebral emboli, given the absence of clinical or neurologic deficits (as assessed by National Institutes of Health Stroke Scale, Modified Rankin Scale, and Montreal Cognitive Assessment). In the 5 patients with 1 new micro embolus, lesions were resolved by 1 month.

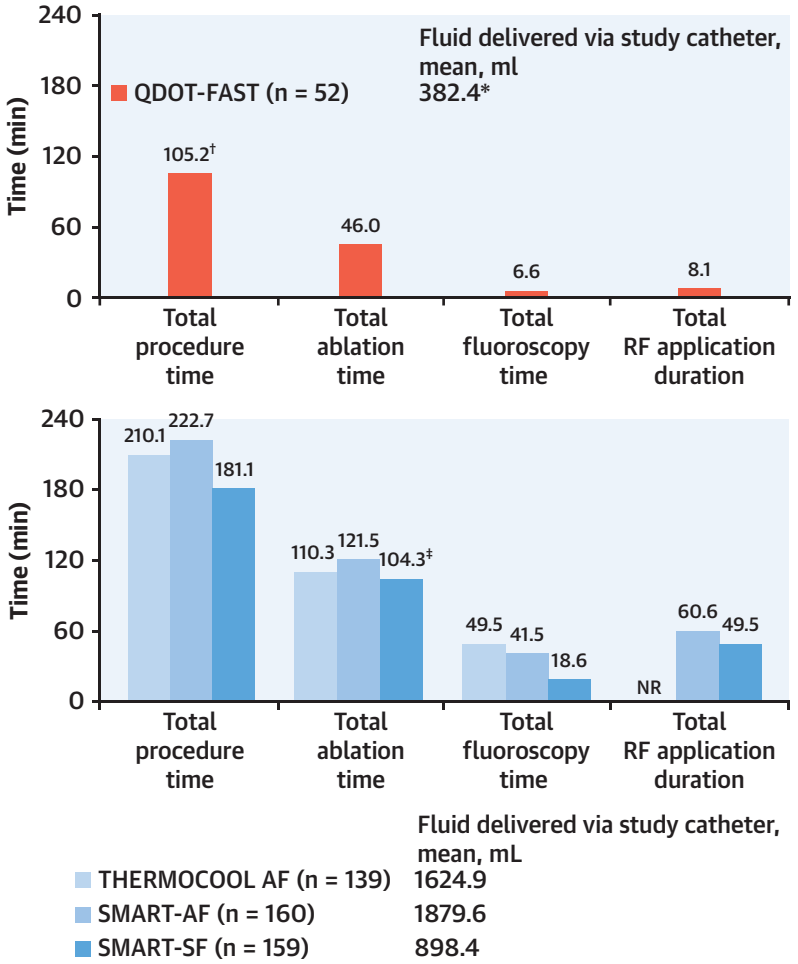
DISCUSSION

This is the first clinical study assessing the feasibility, short-term safety, and effectiveness of ablation with vHPSD (90 W, 4 s) lesions using a novel catheter with temperature-control capability. Short-term procedural success (defined as confirmation of entrance block in all treated PV) was achieved in all 52 patients who underwent ablation. The study showed favorable mean procedure and fluoroscopy times, at 105.2 and 6.6 min, respectively. Only 2 PAE were reported (a pseudoaneurysm and an asymptomatic thromboembolism); there were no reported deaths or instances of atrioesophageal fistula, stroke/cardiovascular accident, transient ischemic attack, PV stenosis, phrenic nerve paralysis, or cardiac tamponade.

SCL were detected in 6 patients (11.5%). Whereas the reported incidence in previous studies of post-

CENTRAL ILLUSTRATION **A Novel Temperature-Controlled RF Ablation Catheter**





*n = 50.
†Includes 20-minute waiting period.
‡Includes 30-minute waiting period.

Reddy, V.Y. et al. J Am Coll Cardiol EP. 2019;5(7):778–86.

Shown on the **left** is the tip of catheter with the microelectrodes and 6 thermocouples. This allows the capacity for very high power–short duration (90 W, 4 s) lesions. As shown on the right, the procedural outcomes in the first-in-human QDOT-FAST study (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation) are substantially improved over other previous multicenter studies. RF = radiofrequency; SMART AF = THERMOCOOL SMARTTOUCH Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation; SMART SF = SMART SF Radiofrequency Ablation Safety Study.

ablation cerebral lesions varies widely, these lesions are typically not associated with neurologic deficits, and most disappear on repeat MRI after 1 to 3 months post-ablation (15,16). In the current study, cerebral lesions were no longer present for 5 of 6 patients after 1 month, and none of the patients showed neurologic symptoms. Although the lack of clinical symptoms in these patients is comforting, it is prudent for operators to be mindful of the potential impact of SCL and apply appropriate procedural workflow (e.g., appropriate pre- and periprocedural anticoagulation strategy, careful introduction and exchange of catheters) to minimize SCL occurrence.

The ability to safely ablate with vHPSD has some theoretical advantages. First, it appears that catheter-tissue contact stability is an important factor contributing to clinical success (7). Sufficient minimum CF is needed to enable contact to provide long-term freedom from recurrent arrhythmia, whereas higher than necessary CF may cause immediate

TABLE 2 Short-Term PV Reconnection

	Effectiveness Population (n = 52)
Left PVI lesion set	7/14 (50.0)
Superior	1/14 (7.1)
Anterior	3/14 (21.4)
Posterior	4/14 (28.6)
Inferior	1/14 (7.1)
Ridge	1/14 (7.1)
Right PVI lesion set	8/14 (57.1)
Anterior	3/14 (21.4)
Posterior	4/14 (28.6)
Inferior	2/14 (14.3)
Ridge	1/14 (7.1)

Values are n/N (%).
PV = pulmonary vein; PVI = pulmonary vein isolation.

complications such as thrombus from steam pops or atrial perforation (7). During vHPSD ablation, the negative effects of CF instability may be mitigated because lesion creation is achieved in a very short duration of time, before stability becomes a consideration (9). Indeed, in preclinical studies, the quality of the lesions appears more homogeneous than with standard ablation (Online Figure 1) (9,17). Of course, greater degrees of instability may attenuate or frustrate the efficacy of even vHPSD lesions.

Second, a crucial safety consideration for AF ablation is minimizing damage to collateral tissues. It has been suggested in preclinical models that vHPSD ablation minimizes conductive heating and subsequent damage to collateral tissues, such as the esophagus, potentially minimizing the risk of atrioesophageal fistula (9-11,18). The absence of an atrioesophageal fistula in our study was encouraging; however, it should be recognized that 52 patients is too limited a number to determine whether an atrioesophageal fistula can truly be avoided by these vHPSD lesions. Indeed, the single case of esophageal ulcer hemorrhage observed in our study is a reminder that 1 must remain vigilant to ensure that complication rates do not escalate with the vHPSD strategy.

TABLE 3 PAE in the Safety Population (n = 52)

	PAE	Relationship With Device or Procedure
Total PAE	2 (3.8)	
Death	0	–
Atrioesophageal fistula*	0	–
Cardiac tamponade/perforation	0	–
Myocardial infarction	0	–
Stroke	0	–
Cerebrovascular accident	0	–
Thromboembolism	1 (1.9)	Possibly related to device; probably related to procedure
Transient ischemic attack	0	–
Phrenic nerve paralysis	0	–
PV stenosis*	0	–
Major vascular access complication or bleeding	1 (1.9)	Not related to device; possibly related to procedure

Values are n (%). *Device- or procedure-related death, PV stenosis, and atrioesophageal fistula that occur >1 week (7 days) post-procedure are considered and analyzed as PAE.
PAE = primary adverse event; PV = pulmonary vein.

There have been some published data on ablation with higher than standard power settings, usually 45 to 50 W, with currently available ablation catheters (12,19). However, these largely retrospective studies were performed at a small number of sites with limited analysis of safety endpoints. In addition, real-time tissue temperature monitoring was not possible with these catheters. On the other hand, another temperature-sensing irrigated catheter with a diamond-impregnated tip was shown to significantly reduce procedure time (20). However, this catheter was limited to 50 W and thus was unable to deliver 4-s vHPSD lesions; lesions averaged 18.8 ± 1.9 s each with this catheter (20). It is important to note that the vHPSD ablation (90 W, 4 s) described by the QDOT-FAST study is different than all previous studies with a limit of 50 W. The ability of the novel vHPSD module to modulate power based on temperature reduces the potential for electrode and tissue overheating, which could, in turn, help avoid char formation and steam pops (9). The safety profile observed with this novel catheter and algorithm was promising, with a low incidence of PAE and no unexpected adverse device effects. Furthermore, because of the ability to highlight only local potentials and not far field potentials, microelectrodes have been useful to avoid radiofrequency delivery on scar tissue. The safety of vHPSD ablation will be further evaluated in larger clinical studies.

STUDY LIMITATIONS. Point-by-point catheter ablation is limited by the longer procedure time associated with individual lesion creation; this prompted adoption of balloon-based catheters for PVI. Nonetheless, current balloon technologies are mostly limited to PV ablation. The current study demonstrated reduction of procedural time with vHPSD ablation, with shorter procedural times than are typically observed with current commercially available CF and non-CF catheters. Furthermore, fluoroscopy exposure was minimized. The improved efficiencies with this focal ablation may allow operators the option to perform PVI and additional ablation, if needed, while maintaining short procedure

times, comparable to balloon ablation technologies. A preclinical study has shown a reduction of 80% in radiofrequency ablation time with vHPSD ablation using the new catheter (10). The efficiency gain of this ablation catheter/strategy is promising and will need to be further evaluated in larger clinical settings.

The current study has a small sample size. Larger comparative studies with formal hypothesis and statistical power calculations are required to definitively investigate the safety and efficacy of this catheter's new functionalities. Additional studies will be needed to optimize the ablation protocol for vHPSD lesions in different cardiac chambers. Also, as a first-in-human feasibility study, the QDOT-FAST study was designed to only follow patients for 3 months. Additional studies with longer-term follow-up and more robust arrhythmia monitoring are required to verify the long-term effectiveness and correlations between short-term follow-up and arrhythmia recurrence. Similarly, the durability of PVI was not assessed in this study and should be evaluated in a dedicated study with protocol-defined redo procedures.

CONCLUSIONS

This first-in-human study of the vHPSD catheter demonstrated its clinical feasibility and associated safety. Larger trials are ongoing to confirm safety and long-term effectiveness of this novel ablation strategy.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Radiofrequency ablation with vHPSD (90 W / 4 s) lesions allows rapid ablation times for PVI.

TRANSLATIONAL OUTLOOK: Although this multicenter, first-in-human study revealed that vHPSD ablation can safely achieve the short-term electrical endpoint of PVI, additional prospective studies are necessary to assess for the durability of PVI, long-term freedom from recurrent atrial arrhythmias, and safety of posterior wall ablation with regard to the esophagus.

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APPENDIX For a supplemental Methods section and figures, please see the online version of this paper.