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Rapid Point-by-Point Pulmonary Vein Isolation*

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Keywords

atrial fibrillation; pulmonary vein isolation; very high power-short duration

Refinement of pulmonary vein isolation (PVI) is an important goal in treating patients with atrial fibrillation (AF). The efficacy of PVI (1–3) varies among patient groups (4), and recurrent AF is often associated with recovery of PV conduction, although strategies aimed at better lesion formation have reduced this problem (5,6). Further improvements in electrical isolation of the PVs would thus be expected to improve outcomes and address mechanistic questions about how PV activity relates to AF recurrence (7,8). From a safety perspective, long-duration lesions, even at reduced power on the posterior wall, may predispose to esophageal injury. The time efficiency of PVI has improved by using various balloon catheters (3,9,10), yet such devices are shaped to fit the PV antra and are cumbersome for ablating extra-PV atrial tachycardia episodes or extra-PV substrates. Thus, strategies to improve the time efficiency and safety profile of point-by-point ablation would be welcome, bearing in mind that some approaches to expedite PVI might have inadvertently led to higher risk of atrioesophageal fistulae (11) and cerebral emboli (12).

In this issue of JACC: *Clinical Electrophysiology*, Reddy et al. (13) report on the 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; NCT03459196) nonrandomized multicenter study of the safety and acute efficacy of a novel catheter for very-high power (90W)-short duration (4 s) (vHPSD) ablation for paroxysmal AF. The vHPSD catheter (Thermocool Smarttouch model

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SF-5D, Biosense Webster, Diamond Bar, California) is equipped with microelectrodes and thermocouples to modulate power and irrigation rate in real time and thus maintain target temperature during ablation. PVI was achieved in 52 patients, by using the catheter in fast mode (vHPSD), with procedure times of 105.2 ± 24.7 min, fluoroscopy times of 6.6 ± 8.2 min, and in 49 of 52 patients in sinus rhythm at 3 months (some taking medications). Adverse events included 1 femoral pseudoaneurysm, 1 hemorrhagic esophageal ulcer, and 6 subclinical cerebral lesions as shown on cardiac magnetic resonance (CMR) imaging.

This is an important first clinical report of a technology with the potential to change the paradigm of radiofrequency PVI for AF. The efficacy of lesion formation by using this approach was previously validated in a canine model published by Leshem et al. (14). The authors' conclusion that vHPSD ablation may expedite PVI compared to lower power and longer duration energy delivery is not actually supported directly, due to the lack of a prospective control group, but is likely to be correct ultimately. Nevertheless, direct comparisons are needed because fluoroscopy times have fallen for point-by-point ablation, largely because of catheter visualization and contact force display with the latest generation mapping systems. Furthermore, the field is already moving to relatively high power and short duration treatment of lesions with clinically available catheters, which also reduce procedure times.

One limitation of this study is that it was not focused on efficacy. Even though this was a feasibility study of vHPSD, rigorous arrhythmia monitoring beyond the blanking period would have enhanced the study and is an important factor in the calculus of whether the technology is improved compared to that of existing catheters. Recording the presence of sinus rhythm at 3 months is encouraging but difficult to interpret in patients with paroxysmal AF, some of whom were still taking antiarrhythmic medications. Examining first-pass PVI data, the authors should be congratulated for confirming PV entrance block after adenosine or isoproterenol challenge. However, the relatively high rates of PV reconnection shown in Table 2 of Reddy et al. (13) suggest either poor interlesional distance control or ineffective lesions. Thus, lesion titration with this new technology may not yet be optimized in patients, particularly for various contact force targets, despite validation in animal models (14).

Safety monitoring in the study was well done. In particular, the authors screened for cerebral lesions with CMR within 72 h before ablation and 72 h after ablation. If cerebral lesions were identified or neurological symptoms ensued, follow-up included CMR and neurological assessments. There were no defined major adverse events, but it is unclear how to interpret the 12% rate of subclinical cerebral lesions (n = 6), including 1 patient with an asymptomatic cerebral infarct (new microemboli on CMR which persisted at 5 months). Of the 6 patients, only 1 did not receive anticoagulation therapy.

The next study of QDOT, listed in the Clinical Trials database is a single-limb safety and efficacy study in 185 patients undergoing systematic electrocardiography monitoring (Q-FFECIENCY [Evaluation of QDOT Micro Catheter for Pulmonary Vein Isolation in Subjects with Paroxysmal Atrial Fibrillation]; NCT03775512). Comparison to other methods may not be expected in a feasibility study, but it is a necessary next step in validating the vHPSD technology. Comparisons should ideally include single-shot balloon

catheters, as well as high-power short-duration ablation with existing catheters. Future studies should also include patient-reported outcomes and quality of life indicators (15).

In conclusion, Reddy et al. (13) should be congratulated on this first clinical study of the vHPSD point-by-point ablation for PVI, which has the potential to shorten procedure times and retain the versatility of conventional point-by-point catheters. As with any new cardiac ablation technology, safe and effective energy titration is critical to success, and additional comparative data for safety and efficacy are needed to understand the true impact of this technology. We eagerly anticipate further developments in this field.

REFERENCES

1. Verma A, Jiang CY, Betts TR, et al. Approaches to catheter ablation for persistent atrial fibrillation. N Engl J Med 2015;372:1812–22. [PubMed: 25946280]
2. Vogler J, Willems S, Sultan A, et al. Pulmonary vein isolation versus defragmentation: the CHASE-AF clinical trial. J Am Coll Cardiol 2015;66: 2743–52. [PubMed: 26700836]
3. Kuck KH, Brugada J, Furnkranz A, et al. Cryoballoon or radiofrequency ablation for paroxysmal atrial fibrillation. N Engl J Med 2016;74: 2235–45.
4. Clarnette JA, Brooks AG, Mahajan R, et al. Outcomes of persistent and long–standing persistent atrial fibrillation ablation: a systematic review and meta-analysis. Europace 2018;20:366–76.
5. De Pooter J, Strisciuglio T, El Haddad M, et al. Pulmonary vein reconnection no longer occurs in the majority of patients after a single pulmonary vein isolation procedure. J Am Coll Cardiol EP 2019;5:295–305.
6. Phlips T, Taghji P, El Haddad M, et al. Improving procedural and one-year outcome after contact force-guided pulmonary vein isolation: the role of interlesion distance, ablation index, and contact force variability in the “CLOSE”-protocol. Europace 2018;20:419–27. [PubMed: 29016750]
7. Nery PB, Belliveau D, Nair GM, et al. Relationship between pulmonary vein reconnection and atrial fibrillation recurrence: a systematic review and meta-analysis. J Am Coll Cardiol EP 2016;2: 474–83.
8. Prabhu S, Kalla M, Peck KY, et al. Pulmonary vein activity does not predict the outcome of catheter ablation for persistent atrial fibrillation: a long-term multicenter prospective study. Heart Rhythm 2018;15:980–6. [PubMed: 29501669]
9. Dukkipati SR, Cuoco F, Kutinsky I, et al. Pulmonary vein isolation using the visually guided laser balloon: a prospective, multicenter, and randomized comparison to standard radiofrequency ablation. J Am Coll Cardiol 2015;66: 1350–60. [PubMed: 26383722]
10. Yamasaki H, Aonuma K, Shinoda Y, et al. Initial result of antrum pulmonary vein isolation using the radiofrequency hot-balloon catheter with single-shot technique. J Am Coll Cardiol EP 2019; 5:354–63.
11. Vurma M, Dang L, Brunner-La Rocca HP, et al. Safety and efficacy of the nMARQ catheter for paroxysmal and persistent atrial fibrillation. Europace 2016;18:1164–9. [PubMed: 27247003]
12. Michaud GF. Asymptomatic cerebral emboli with the PVAC gold: worth another look? J Am Coll Cardiol EP 2019;5:327–9.
13. Reddy VY, Grimaldi M, De Potter T, et al. Pulmonary vein isolation with very high power, short duration, temperature-controlled lesions: the QDOT-FAST trial. J Am Coll Cardiol EP 2019;5: 778–86.
14. Leshem E, Zilberman I, Tschabrunn CM, et al. High-power and short-duration ablation for pulmonary vein isolation: biophysical characterization. J Am Coll Cardiol EP 2018;4:467–79.
15. Steinberg BA, Dorian P, Anstrom KJ, et al. Patient reported outcomes in atrial fibrillation research: results of a clinicaltrials.gov analysis. J Am Coll Cardiol EP 2019;5:599–605.