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How to achieve durable pulmonary vein isolation: Use the force

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In this issue of *HeartRhythm*, Reddy et al¹ report the 12-month clinical results of the TOuCh + for CATHeter Ablation (TOCCATA) study, in which pulmonary vein isolation (PVI) was performed in 32 patients with paroxysmal atrial fibrillation (AF) using a novel open-irrigated radiofrequency (RF) ablation catheter (TactiCath, Endosense SA, Geneva, Switzerland) with a contact force (CF) sensor at the distal tip. The main conclusion of the study was that average CF during ablation was an important determinant of clinical outcome. In the study, a mean CF >20 g predicted the best outcomes (80% freedom from AF recurrence over 12 months), whereas all 5 patients with mean CF <10 g had evidence of AF recurrence during the follow-up period. Although the study population was small, these statistically significant results help to validate the importance of CF as an important determinant of clinical outcome after AF ablation.

The rationale for the use of CF sensing during AF is based, in part, on key translational experiments performed by Haines and others over 20 years ago showing that CF is a key determinant of ablation lesion size.² When ablation is performed with a standard catheter without CF-sensing capability, the operator often relies on tactile feedback or data from impedance monitoring and intracardiac ultrasound. Although tactile feedback may be helpful, the mean CF during left atrial ablation with operators blinded to CF measurement has been shown to be highly variable, ranging from 12 ± 10 g to 39 ± 29 g.³ Fortunately, now it is possible to measure CF directly during ablation. Using 3 optical fibers (0.125-mm diameter) and a deformable force sensor (elastic polymer) between the distal second and third catheter electrodes, the TactiCath catheter (Endosense SA) measures force based on microdeformations at the catheter tip. During ablation with the TactiCath system, CF is measured 10 times per second and displayed continuously. With this mechanism, axial, oblique (45°), and lateral CF can be measured with a high degree of accuracy. Furthermore, CF correlates very well with lesion depth, diameter, and volume.⁴ Of note, the CF may be quantified as the mean force or the force–time integral (FTI) at that site. The FTI represents the area under the force–time curve and has been shown to predict radiofrequency lesion size.⁵

PVI is an excellent application for CF monitoring due to the significant long-term rates of pulmonary vein reconnection after the procedure associated with dormant conduction between the pulmonary veins and the left atrium in the setting of suboptimal RF lesion formation.⁶ Achieving optimal CF is important even for the first ablation application at each site because tissue edema develops quickly during ablation and limits the effectiveness of additional ablation. The finding of a much lower success rate in patients with just 2 or more RF applications having very low mean CF (<5 g) (40% vs 75%, $P = .03$) highlights the importance of effective RF applications from the start.¹ As a result, measuring CF

throughout the ablation procedure may help avoid suboptimal or ineffective RF applications that limit the effectiveness of subsequent ablation.

The present report from the TOCCATA investigators builds on their previous safety report with this catheter published earlier this year in *HeartRhythm*.³ The 77 patients enrolled in this overall TOCCATA study included 43 with right-sided supraventricular tachycardias and 34 with AF. Of note, the TOCCATA protocol included a contact mapping portion in which the operator was blinded to CF; however, CF data were made available to the operator during the ablation part of the procedure. High CF events in this study were defined as increases to >100 g of CF during the procedure. The one perforation event in the study was preceded by an elevated CF of 137 g during catheter manipulation, highlighting the fact that perforation does not have to occur during ablation but rather can occur with just catheter manipulation.

Reddy et al¹ present clinical follow-up data for 32 of these 34 AF patients, with 1 patient excluded for persistent AF and withdrawal of the other patient prior to 3 months of follow-up. The outcome of interest in these 32 patients was the absence of sustained AF, atrial flutter, or atrial tachycardia for over 30 seconds during 12 months of follow-up or confirmed isolation of all 4 pulmonary veins during a repeat procedure. Recurrent arrhythmia was assessed both clinically and with 7-day Holter monitoring performed 3 months, 6 months, and 12 months after ablation. Based on these criteria, only 15 patients remained without any recurrences during the 12 months after ablation, but a total of 17 patients were classified as having successful outcomes because 2 additional patients with recurrences had confirmed PVI at the time of the second procedure. Of note, a successful outcome did not require patients to be off antiarrhythmic drugs, and no blanking periods were applied. The reader should note the differences between this definition of 1-year success and the definition provided in the most recent HRS/ EHRA/ECAS Expert Consensus Statement on Atrial Fibrillation Ablation, in which 1-year success is defined as freedom from AF/atrial flutter/atrial tachycardia off antiarrhythmic drug therapy as assessed from the end of a 3-month blanking period to 12 months following the ablation procedure.⁷

The reader should also note that the statistically significant comparisons reported in the paper were only between the extremes of CF because the small sample size limited the statistical power of the study. For example, although the success rate for the 10 patients with >20 g of mean CF appears to be qualitatively higher than that for the 17 patients with 10 to 20 g of mean CF, the difference in success rates between the 17 patients with >20 g of mean CF and the 5 patients with <10 g of mean CF ($P = .01$) was the statistically significant result. Similarly, only the difference between the 13 patients with FTI >1000 gs and the 8 patients with FTI <500 gs was statistically significant.

The reader should also make particular note of the fact that, in the TOCCATA study, the ablation part of the procedure was not blinded to CF. These operators presumably were aware of prior animal data with this catheter showing that a CF of 20 to 30 g during ablation at 30 W would be expected to give a significantly greater lesion volume compared with a CF of 10 g at the same power.⁴ Why, then, were they not able to make the necessary adjustments to achieve a higher mean CF for the patients in the low CF group? Although it is possible they were conservative, it is more likely that they wanted to achieve higher CFs but had difficulty doing so. This implies that use of the CF catheter alone is not sufficient to achieve higher success rates, likely because patient and technical factors limit achievement of adequate CF in selected patients. Of note, fluoroscopy times in the <10-g group were 55.0 ± 32.0 minutes, compared with 32.3 ± 15.9 minutes and 32.2 ± 23.6 minutes in the other 2 groups, respectively. The higher fluoroscopy time in the low CF group suggests perhaps some difficulty with catheter manipulation or less use of intracardiac echocardiography. In

addition, their Table 3 shows that the patients in the <10-g group had a trend for a greater prevalence of coexisting cardiac disorders, and there was a statistically significant difference in left atrial size among the 3 groups.

Integration of intracardiac ultrasound technology during left atrial ablation may be a critical adjunctive tool in these patients in order to improve catheter contact and achieve higher CF.⁸ In addition, administration of adenosine after apparent PVI to assess dormant conduction⁹ or pacing to test for excitable tissue along the ablation line¹⁰ may allow for additional targeted ablation and help compensate for gaps left behind in selected patients. Steerable sheaths and the use of general anesthesia are also useful adjunctive measures to improve catheter stability and CF, particularly in difficult patients.

CF monitoring during AF represents a very exciting opportunity to achieve higher rates of durable PVI. The present study provides important validation of prior translational studies showing that improved CF results in more effective ablation lesions. As we gain more experience with CF-assisted AF ablation, we will hopefully gain a better understanding of how best to use CF monitoring during ablation to maximize the rate of durable PVI during ablation of AF.

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