Top EP Publications in 2021 … and What to Look For in 2022

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Dear Readers,

Many high-impact papers were published in 2021, and many more are anticipated during 2022. Below are five studies that were published in 2021 or were shared in some form with anticipated full publication next year. The list is somewhat arbitrary, but covers the spectrum of topics for which electrophysiologists are looking for answers.

1. **LAAOS III.**[1] This was a multicenter, randomized trial of left atrial appendage occlusion (LAAO) versus no occlusion in nearly 3000 patients with atrial fibrillation (AF) and a CHA_2D_2-VASc score of ≥2 undergoing cardiac surgery. One-third of patients had concomitant surgical ablation for AF. All patients were expected to remain on oral anticoagulation, and 77% did. The study found that after three years, 4.8% of patients who had LAAO had a stroke or systemic embolism compared to 7% of patients who did not ($P<.001$). The two take-home lessons from this paper are that closing the LAA in patients who have a history of AF and are undergoing cardiac surgery should now be standard of care, and that patients with AF who have undergone surgical removal of their LAA should remain on anticoagulation unless they have significant contraindications.

2. **DECAAF II.**[2] This study was a prospective, multicenter, randomized trial of conventional pulmonary vein isolation (PVI) versus PVI plus fibrosis-guided ablation as detected by late gadolinium enhancement (LGE) on cardiac magnetic resonance imaging (MRI) in ~850 patients with AF. Data were presented as a Hot Line Session during the European Society of Cardiology Congress in August 2021. Although the full study design has already been published, publication of the results is still pending. The main result of the trial from an intention-to-treat analysis of the primary endpoint was that there was no difference between the two groups in the proportion free of atrial arrhythmia recurrence. Although there is much information from this trial that requires further analysis and other lessons that may be learned from the results of the imaging after ablation, the main message from this trial is that PVI plus fibrosis-guided ablation is not superior to conventional PVI for patients with AF and fibrosis as detected with an MRI. Studies of scar-based ablation as detected using atrial electrogram analysis may yield different results.

3. **AMAZE.**[3] The results of the aMAZE trial have yet to be presented at a medical forum and the study has not yet been published. However, the CEO of the sponsor, AtriCure, presented preliminary findings at an investigator's meeting this year and publication of the results is imminent. This was a prospective, multicenter, randomized, controlled trial to evaluate the safety and efficacy of the LARIAT Suture Delivery System to percutaneously isolate and ligate the LAA as an adjunct to PVI not to prevent stroke, but to treat symptomatic persistent or longstanding persistent AF. By January 2020, 600 patients were treated at 53 sites. The primary endpoint was freedom from AF >30 seconds off antiarrhythmic drugs at one year. Initial indications are that the primary safety goal (10% freedom for major adverse events) was met, but the primary efficacy endpoint was not. The key take-home message of this trial is that despite data that electrical isolation of the appendage improves outcomes with ablation for persistent AF, ligation of the LAA did not help maintain sinus rhythm.

4. **Four-dimensional (4D) ICE.**[4] Rachel Kaplan, MD, and colleagues published their early experience using a 4D intracardiac echocardiography (ICE) catheter (VeriSight Pro, Philips) during EP procedures in 10 patients. Their experience demonstrated that imaging with this novel 4D ICE catheter using digital steering and 4D image acquisition was safe and allowed for creation of high-quality 2D and 4D images in real time during EP procedures. Vivek Reddy, MD, presented similar data using the 4D NuVision ICE catheter (Biosense Webster) at a late-breaking clinical trial at Heart Rhythm 2021. Nine physicians used the catheter in 28 patients to guide catheter ablation and LAAO procedures, and found that it met all safety and performance endpoints. Expect this paper to be published in 2022. Further use of 4D ICE will be needed to determine its added value for each type of EP procedure.

5. **Extravascular ICD.**[5] The extravascular implantable cardioverter defibrillator (EV ICD) involves percutaneous placement of a lead under the sternum overlying the heart and connection to a subcutaneous generator implanted at the left midaxillary line. This allows for lower defibrillation energy requirements compared to the commercially available subcutaneous defibrillator with a lead that is on top of the sternum, and may allow for direct myocardial capture to provide antitachycardia and bradycardia pacing. The EV ICD pivotal study plan was published in 2021. This is a prospective, multicenter, single-arm, non-randomized, premarket clinical study designed to examine the safety and acute efficacy of the EV ICD system. The study will enroll up to 400 patients with an indication for an ICD. The primary endpoints of the study will be freedom from major complications at six months with a target of >79%, and successful defibrillation testing at the time of implantation with a target greater than 88%. Secondary endpoints will include antitachycardia pacing performance, electrical performance, extracardiac pacing sensation, asystole pacing, and appropriate and inappropriate shocks. This study was recently closed to enrollment and given that the primary endpoint will be measured at six months, expect publication of these pivotal trial results in 2022.

Considerable progress has occurred in our field in the last year despite a global pandemic. It appears that many aspects of interventional electrophysiology are being improved and advanced, and that exciting new developments are around the corner. ■

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