COMMENTARY

Are We Inflating the Success Rate of AF Ablation?

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Try this experiment. The next time you admit a patient for rapid tachycardia a week after an atrial fibrillation (AF) ablation, tell him the arrhythmia doesn't count because it occurred during the "blanking period."

Since the inception of AF ablation, electrophysiologists have considered it normal to exclude episodes of atrial arrhythmia up to 3 months after the procedure when measuring procedural success. Nearly every trial ever done for AF ablation includes such a blanking period.

Yet, our patient is in a lumpy hospital bed with scratchy sheets, an IV in his arm; he is served terrible food, woken up for vital signs at 3 AM, for blood work at 4 AM, and yet another person does his ECG at 5 AM. He surely has a different view of whether this arrhythmia counts.

This common scenario prompted an editorial I co-wrote, titled "Patients' lives don't pause for blanking periods."

I will outline our case for eliminating the blanking period after AF ablation.

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Why Don't Early Recurrences of AF Count?

The blanking period began with the decades-old observation that thermal ablation to isolate the pulmonary veins often results in early recurrences of AF or atrial flutter. These early tachycardias were associated with a higher rate of late recurrences of AF (procedural failure), but the correlation was not perfect. Sometimes the early AF episodes would resolve and patients would remain free of AF over the long term.

Early recurrences can occur because of true procedural failure, either due to reconnection of the pulmonary veins (the pulmonary vein isolation did not hold) or because the wrong area was targeted. Other potential causes of early

recurrence that dissipates with time are direct mechanical trauma, inflammation, and/or autonomic changes, similar to the proposed causes of AF after cardiac surgery.

These latter causes led to the establishment of a 90-day blanking period after the procedure. The best argument for the blanking period is that it encourages us to wait before doing a repeat ablation, and because many of these early AF episodes resolve, we avoid overtreatment.

But I see better reasons to eliminate the blanking period.

Reasons to Eliminate the Blanking Period

The first is that it inflates the true success rate of AF ablation. A recent study from the Canadian CIRCA-DOSE trialists found that the success rate of the procedure dropped from 55% to 50% if you included early recurrences of AF. Swiss authors confirmed this finding in a reanalysis of a randomized controlled trial of two cryoballoons.

But you hardly need studies to know that excluding recurrences during the blanking period favors the procedure. This is important in trials that measure AF recurrence as a primary endpoint. Consider that some trials end at a year, so a 90-day blanking period excludes 25% of the follow-up period.

The second reason to eliminate the blanking period is that I can think of few other areas of cardiology that use one. For example, if the ISCHEMIA trial comparing invasive vs conservative management of patients with a positive ischemic stress test had a blanking period, the results would have been different.

The primary outcome of the ISCHEMIA trial was a composite of myocardial infarction (MI), hospitalization for unstable angina or heart failure, cardiovascular death, or resuscitated cardiac arrest. The main result found no

significant differences between the two strategies. Debate centered on rates of MI. The main result counted all MIs (including periprocedural MIs). In a secondary analysis that excluded periprocedural MI (ie, a blanking period), the invasive arm showed a significant reduction in MI (hazard ratio, 0.67; 95% CI, 0.53-0.83).

I have been critical of the OPTION trial, which compared left atrial appendage closure added to AF ablation with direct-acting oral anticoagulants after AF ablation. Trialists chose a primary safety endpoint that excluded bleeding at the time of the procedure. Using a peri-procedural blanking period allowed the investigators to declare the LAAC/Ablation strategy superior in safety to DOAC/Ablation. Without a blanking period, superiority would not have been established. Of course, patients cannot exclude bleeding events around the procedure.

Pulsed Field Ablation

The third reason to eliminate the blanking period concerns the advance of pulsed field ablation. Pulsed field ablation uses electrical rather than thermal energy. Although its efficacy and safety have been found similar to thermal ablation, there are probably different postprocedural effects.

This multicenter observational study of more than 300 patients treated with pulsed field ablation found that early recurrence of atrial tachyarrhythmias was common and 100% of patients who had recurrences in the second or third month post-procedure had late recurrences.

German electrophysiologist and early adopter of pulsed-field ablation Stefano Bordignon emailed me that he increasingly believes that a recurrence after pulsed field ablation at any time should count as a true recurrence. He reasons that in experienced hands, pulsed field ablation is so effective at isolating the pulmonary vein, that a recurrence indicates a nonresponder and someone who may benefit from an early re-do ablation.

Bordignon also believes that many of the treatment failures observed with pulsed field ablation are due to poor patient selection. Because the procedure is so fast and safe, doctors are offering it to patients who previously would have been ruled out for ablation due to likely treatment failure. For many of these patients, comorbidities that won't be "fixed" by ablation are the drivers of their AF.

Conclusions

It is time to right a wrong. Blanking periods bias in favor of ablation, complicate trial interpretation, and ignore patient-centered outcomes. Few if any other areas of cardiology exclude the days and weeks after a procedure.

The advent of pulsed field ablation further exposes the problems with blanking periods because it is increasingly clear that AF recurrences after pulsed field ablation predict procedural failure.

Patients can't pause to ignore their symptoms after ablation; neither should doctors. To the purists who insist on a blanking period, we can make it a secondary endpoint of trials. The primary endpoint should be all episodes from the moment of randomization, as was done in the ISCHEMIA trial.

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