Randomized Trial Getting Started

AF Ablation *from page 1*

"It was quite striking and really caught us off guard that the 3-year mortality rate of atrial fibrillation patients on what their physicians felt was best medical therapy was 23.5%," he noted.

The rate of hospitalization for heart failure was 3.8% in the AF ablation cohort, 3.7% in medically managed controls with AF, and 1.8% in the control group with no history of AF. Of note, the baseline prevalence of heart failure was 30% in the AF ablation group, significantly higher than the 24% in the medically managed AF controls and the 15% in the no-AF controls.

'The 3-year mortality rate of atrial fibrillation patients on what their physicians felt was best medical therapy was 23.5%.'

Dr. Elaine M. Hylek, cochair of the session, said that she remained unconvinced by the large Utah study.

"The challenge for any observational study, no matter how well designed, is that without the benefit of randomization it's really tough to control for the confounder of the initial selection bias, or confounding by indication," said Dr. Hylek of Boston University.

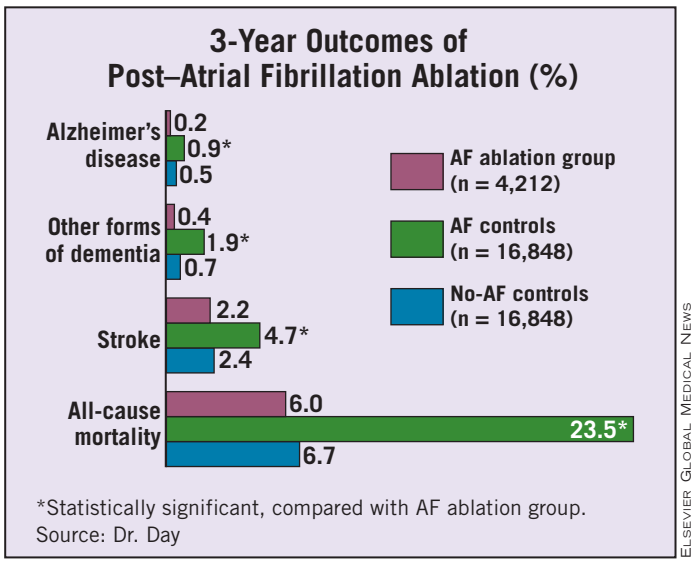
If it were possible to stratify the patients based on Charlson Comorbidity Index scores or another reference point, though, that would help neutralize the selection bias limitation, she added.

Dr. Day agreed. "We tried the best we could to compensate for the limitations of this type of study design by including every patient within an entire large health care system and then also having two matched control arms. Still, in the absence of a randomized, controlled trial—and we're still at least 4-5 years away from data from the ongoing CABANA trial—there are limitations," he conceded. The CABANA (Catheter Ablation Versus Antiarrhythmic Drug Therapy for Atrial Fibrillation) trial is a 3,000-patient, 5-year randomized study that recently began enrollment at a planned 180 centers worldwide.

In an interview, Dr. Day said that he and his coworkers are planning to reanalyze their study findings based on postablation AF burden, since in the first analysis a patient who went from hours or days per month spent in AF preablation to a couple of minutes in AF per 6 months post ablation would be categorized as a treatment failure.

The mechanism by which AF ablation might eliminate the excess risk of Alzheimer's disease is unknown. One theory is that AF might predispose to subclinical strokes too small to be visible on brain MRI, which then promote amyloid plaque deposition. Alternatively, the great fluctuations in heart rate and blood pressure that occur in AF episodes might create an environment that predisposes to brain amyloid plaque. Another possibility is that the answer lies in the inflammatory state that's common to both AF and Alzheimer's disease, he said. ■

Disclosures: *Dr. Day reported that he serves as a consultant to Boston Scientific and St. Jude Medical.*



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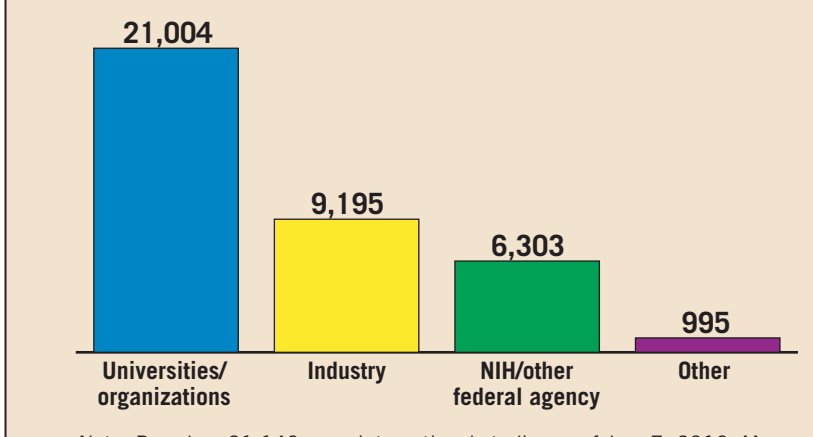

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