Response to Letter by Willey

Response:

Dr Willey raises the important issue of what constitutes an “episode” of atrial fibrillation (AF). There are several aspects to that issue. In the cardiology literature, an “episode” is indeed defined as lasting ≥30 seconds in a number of authoritative sources.1–3 In our article, the definition used was a minimum of 5 minutes. The sole rationale for this criterion, as stated in the article, was to exclude brief periods of atrial oversensing, which can lead to false-positive recordings of AF with the devices used in our study. Implantable devices can and do record episodes having durations in the range of 30 seconds to 5 minutes. However, these very brief episodes may need manual review of the stored episode electrograms to determine their true character.

Dr Willey points out a statement in the guidelines2 about episodes <30 seconds perhaps being of importance in “symptomatic” patients, a category that might include those with previous stroke. We agree that the issue of how much AF is important in conferring future or reflecting prior stroke risk remains unresolved. More research on this question is needed and indeed our estimate of the percentage of patients with stroke with newly detected AF may be conservative.

Dr Willey also speculates that external monitoring for 30 days may be “sufficient” to detect “clinically important AF.” Only a direct comparison of monitoring techniques can answer that question. However, it seems unlikely in our view that external monitoring would be as sensitive as that provided by implantable devices.4 One of the significant limitations of external monitoring devices is that patient compliance is often quite low.5 The CRYptogenic Stroke And underLYing Atrial Fibrillation (CRYSTAL AF) study6 is presently comparing the incidence of AF among patients with cryptogenic stroke who are randomized to external monitoring with a subcutaneous device or with traditional external methods. The results of this ongoing study will begin to address the core of the question raised by Dr Willey; namely, is it better to monitor continuously for an extended period of time, even if it means possibly overlooking extremely brief episodes of AF, or is it better to monitor for much shorter durations with a technology that is capable of detecting even the briefest of episodes?

In our “Discussion,” we noted that subcutaneous devices with continuous atrial arrhythmia monitoring capabilities are now available. This comment directly addressed the issue of the generalizability of our approach to detecting atrial tachycardia/AF beyond using the recording capabilities of implanted cardiac devices such as pacemakers and implantable cardioverter-defibrillators. At the present time, such subcutaneous devices are only offered by Medtronic, although other manufacturers are also developing subcutaneous devices with AF detection algorithms. Dr Willey felt that, “Further statements on the role of the funding source may have been helpful.” We felt we were fully transparent about the relationship of Medtronic to this study. In the sections “Sources of Funding” and “Disclosures,” we made clear that the study was funded by Medtronic and that the authors were Medtronic employees or paid consultants of Medtronic. This is how Medtronic and other device manufacturers support peer-reviewed research to assess the clinical value of its products.

Disclosures

P.D.Z. is an employee and shareholder of Medtronic. T.V.G. and E.G.D. are consultants for Medtronic and speakers for Medtronic, St. Jude Medical and Boston Scientific. D.G.W. is a consultant for Medtronic and Biotronik. D.E.S. and M.D.E. are consultants for Medtronic.

Paul D. Ziegler, MS
Medtronic
Mounds View, Minn

Taya V. Glotzer, MD
Hackensack University Medical Center
Hackensack, NJ

Emile G. Daoud, MD
Ohio State University Medical Center
Columbus, Ohio

D. George Wyse, MD, PhD
Libin Cardiovascular Institute of Alberta
Alberta, Canada

Daniel E. Singer, MD
Massachusetts General Hospital
Boston, Mass

Michael D. Ezekowitz, MD, PhD
Lankenau Institute for Medical Research
 Wynnewood, Pa


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Paul D. Ziegler, Taya V. Glotzer, Emile G. Daoud, D. George Wyse, Daniel E. Singer and Michael D. Ezekowitz

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