Response to Call for a Re-evaluation of the American Heart Association’s Standpoint Concerning Device-Guided Slow Breathing Using the RESPeRATE Device

We thank Dr van Dijk et al for their interest in, and contributions to our understanding of, device-guided slow breathing as an alternative approach to lowering blood pressure.1 We regret that the meta-analysis reported in our overview1 was completed before the publication of their recent trial, which found no significant differences in office blood pressure responses among 45 diabetes mellitus patients.3 In our review as part of the American Heart Association scientific statement,2 we were indeed careful to point out many of the same methodological issues as raised in their letter, their recent trial,3 and in an independent meta-analysis.4 We expressed similar concerns about the possibility of inadequate statistical power, the nature of the selected control interventions, and the small number of published studies performed independently of the device’s manufacturer. We recommended,1 as do Dr van Dijk et al, that further evidence of the device’s efficacy be sought, particularly in studies longer than 9 weeks, and in larger, broader populations.

The writing group wrestled vigorously with specific class and level of evidence recommendations for device-guided breathing as an alternative approach for lowering blood pressure. We had spirited discussions of whether the previously discussed limitations of study design, statistical power, methods of analysis, and other hallmarks of inferior-quality research should outweigh the significant results of the meta-analyses3,4 that included all published trials. At the conclusion of our deliberations, we decided to provide both the overall results of the inclusive meta-analyses and the strong caveats about the data that constituted them. The writing group felt the overall evidence best fit the American Heart Association’s class IIa criteria (benefit>risk, but additional studies with focused objectives are needed), with the level of evidence B because some conflicting evidence from single randomized trial or nonrandomized studies existed. We refrained from recommending that the procedure should be performed (class I) and concluded only that it is reasonable to perform the procedure (class IIa).1 Despite being of high quality, their study was unfortunately underpowered to detect the expected systolic blood pressure reduction from device-guided slow breathing (−3.67 mmHg; 95% confidence interval, −5.99 to −1.39),4 and thus we do not think that their new findings alone merit an alteration in our prior carefully considered conclusions. However, we were not aware of the death of a subject randomized to the device4 and would now have to change the sentence suggesting that no adverse effects of the device have been reported.

Our intent was, and still is, to foster enthusiasm for longer term, properly controlled, adequately powered randomized trials, as might now be feasible with the RESPeRATE device in the United Kingdom, where the device is reimbursed by the National Health Service if prescribed by a physician or using other (perhaps less expensive and more easily taught) methods of achieving slow respiration. In the end, the modest potential benefits derived from device-guided slow breathing should not be entirely discounted (particularly if corroborated by larger studies), in light of the rising global public health burden of hypertension and the need for multiple evidence-based approaches for its treatment.

Disclosures

None.

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