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

To the Editor:

In the statement of the American Heart Association on nonpharmacological options for blood pressure (BP) reduction, device-guided slow breathing exercises with the RESPeRATE (Intercure Lt) device are mentioned as a reasonable option to support lowering BP.1 The authors conclude that the RESPeRATE (costing ¥299 US Dollar) could harbor benefits for a wide range of populations (class IIA evidence, level of recommendation B).1 We respectfully disagree with this conclusion.

The conclusions presented in the American Heart Association statement are based on several trials that were all subject to methodological flaws as also concluded in a recent meta-analysis.2 Only 1 study showed a significant positive effect of the RESPeRATE device on office-measured BP.3 Unfortunately, this study was not blinded, compared the RESPeRATE with usual care, and was performed by the manufacturer. To overcome these methodological problems, we recently performed an investigator-initiated, double-blind, and sham-controlled trial among patients with type 2 diabetes mellitus and hypertension.4 After 8 weeks there were no changes in BP, with a difference in systolic BP of 2.35 mm Hg (95% confidence interval, −6.50 to 11.20) in favor of the control group. Furthermore, 3 adverse events occurred in the intervention group, of which shortness of breath in 2 cases was probably related to the RESPeRATE device.4

As reckoned by the authors of the American Heart Association advice, there is a need for methodological sound (ie, investigator-initiated, randomized, double-blind, and sham-controlled) studies to assess long-term effectiveness of the RESPeRATE. Nevertheless, on the basis of new data, potential adverse events, high costs, and lack of effect on BP in trials with an adequate control group, we (1) strongly suggest the authors to re-evaluate the American Heart Association scientific standpoint concerning device-guided slow breathing using the RESPeRATE device and (2) wonder whether the authors agree with us that the degree of recommendation should be changed into class III instead of IIA.

Disclosures

None.

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