Non-Drug Blood Pressure-Lowering Device: A Clinical Overview

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Introduction

Reduction of high blood pressure (BP) by non-pharmacological means (i.e. lifestyle modifications) is widely recommended, either as primary prevention or therapy or as adjunctive treatment with antihypertensive drugs. Several recent clinical trials have demonstrated that 8 weeks of daily at-home use of a device that slows breathing rate lowers BP[1-7,].

Mechanism of Action

Inappropriately high sympathetic nervous outflow from the central nervous system is believed to be an important component in the pathophysiology of acute and chronic hypertension that stimulates increases in cardiac output and peripheral resistance. Elevated sympathetic activity is often associated with desensitization of arterial and cardiopulmonary baroreceptors, which leads to increased BP fluctuation and sustained elevations in resting pressures.

Slow breathing (< 10 breaths/minute), especially with prolonged exhalation, appears to reduce sympathetic nerve traffic and thus causes arteriolar dilatation. The process is believed to be initiated by activated pulmonary mechanoreceptors, which respond to the increased tidal volume that accompanies slow breathing, and act in concert with cardiac mechanoreceptors to inhibit sympathetic outflow[8].

Device Description

The new device (RESPeRATE®, InterCure Inc., Fort Lee, NJ) consists of a control box (about the size of a paperback book) containing a microprocessor, a belt-type respiration sensor (which functions as a respiration sensor), and headphones (to provide feedback to the patient). During a session of device-guided breathing, the device analyzes the breathing rate and pattern and creates a personalized melody composed of two distinct tones – one tone for inhalation, one for exhalation. As the patient synchronizes breathing with the tones, the device gradually prolongs the exhalation tone and slows the breathing rate to <10 breaths/minute.

A record of the patient's use of the device is stored in the microprocessor for quantitation of total time of device use and adherence to the regimen.

Clinical Studies

Seven separate studies[1-7] have examined the decrease in office blood pressure for subjects who used the device for 15 minutes/day for 8 weeks, compared to "control" interventions (listening to relaxing music[1] or home BP monitoring[4-5] or both[2]). Four studies were double-blind and randomized[1,2,5,8]; one was controlled and randomized[4], and two were open-label experiences[3,6].

A total of 286 individuals participated in the seven studies: 55% were men; 78% were drug-treated, with average age of 58 years; Body Mass Index of 28 kg/m^2; and initial office BP of 150/90 mmHg (9% pre-hypertensive; 25% Stage 2).

The decrease in office BP after 8 weeks of device-guided breathing among those with uncontrolled hypertension was 14/8 mmHg, compared to control treatment of 9/4 mmHg (p = 0.008 and p = 0.002, respectively for systolic and diastolic BPs). The difference was independent of gender and medication status. Control of BP (< 140/90 mmHg) was seen more commonly in the group that used the device: 26% vs. 4% of those with initial Stage 2 hypertension (> 160/100 mmHg, p < 0.005); and 48% vs. 34% for those with initial Stage 1 hypertension (140-159/90-99 mmHg, p < 0.05).

The drop in office BP was directly related to the duration of slow breathing during the 8 weeks of treatment; those who used the device to achieve slow breathing more than 15 minutes/day had the greatest lowering of office BPs. It usually takes 3-5 weeks to achieve a sustained reduction in home BP.

Larger decreases in office BPs were seen in older individuals and those with higher baseline BPs, whether taking antihypertensive medication or not. Verification of BP lowering has also been seen with home BP measurements (for up to 6 months of use[7]) and ambulatory BP monitoring[3].

Usage Guidelines and Administration

The device is indicated by the US FDA for the reduction of stress and as an adjunctive therapy in hypertension that can be combined with standard antihypertensive drugs and non-pharmacologic interventions.

The clinical situations in which RESPeRATE appears particularly useful are: 1) pre-hypertensives and white-coat or labile hypertensives who might benefit from reducing stress and sympathetic activity; 2) patients with isolated systolic hypertension; and 3) resistant hypertensive patients (uncontrolled BP despite use of a diuretic and at least 2 other medications at maximum dosage).

There are no known contraindications or adverse reactions to use of the device to guide slow breathing.

Patients should be instructed to use the device routinely in 15-minute daily sessions, aiming to accumulate at least 45 minutes of slow breathing per week (as indicated by the device's display). Patients should be made aware that results, just like physical conditioning, may take a few weeks to become fully manifested and that without continued device use, any achieved benefits would likely be diminished.

Summary

Routine use of a device to guide slow breathing significantly lowers office measurements of blood pressure without adverse effects. This modality may be a useful adjunct to current antihypertensive medications and to non-pharmacologic interventions in achieving better blood pressure control.

Reprints, full indication for use and additional information can be found at www.resperate.com/MD .

References

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