

Device-guided Controlled Breathing as a Treatment for Hypertension

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of device-guided breathing to lower blood pressure in clinical practice.

BACKGROUND

Hypertension

Elevated blood pressure is a common, independent risk factor for stroke, coronary heart disease (CHD), congestive heart failure and kidney disease. The risk relationship is progressive and graded throughout the range of blood pressure including the “normal” range.^{1,2} Risk approximately doubles for each increase of 20/10 mm Hg, beginning at 115/75 mm Hg.^{3,4} About 25% of all American adults (> 50 million people) have hypertension, which is defined as a systolic blood pressure (SBP) of ≥ 140 mm Hg and/or a diastolic blood pressure (DBP) of ≥ 90 mm Hg. Risk increases with age- over 50% of Americans 60 years and older have hypertension.^{5,6} The lifetime risk of hypertension is greater than 90%, even for people without hypertension at age 55.⁷

A substantial body of literature documents, with randomized clinical trials, that drug therapy used to lower blood pressure prevents stroke, CHD and heart failure.^{8,9} All of the clinical trials with clinical endpoints identified patients for randomization using office blood pressure measurements.

The relationship between blood pressure and future events has been based on office blood pressure readings. However, office blood pressure measurement is often imprecise. In order to minimize errors and variability, the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood pressure (JNC) recommends a standard protocol for measurement of blood pressure in the office. The patient should be seated in a chair with arm supported at heart level. The most recent caffeine, smoking and exercise should be more than 30 minutes prior to measurement. At least two measurements should be made and the average recorded.¹

Table 1 lists the current categorization of blood pressure for adults, as recommended by JNC VII. These categories should reflect the average of at least two office readings following the standard protocol on each of at least two separate visits.¹

TABLE 1. Classification of Blood Pressure (BP) for Adults

BP Classification	SBP mm Hg	DBP mm Hg
Normal	<120	And <80
Pre-hypertension	120-139	Or 80-89
Stage 1 hypertension	140-159	Or 90-99
Stage 2 hypertension	≥160	Or ≥100

The definition of normal is changing, in part based on the observation that risk of heart attacks, strokes, kidney disease and death is continuous through what was previously considered the normal range of blood pressure. Thus, a person with a blood pressure of 135/85 has twice the risk of cardiovascular disease compared to a patient with a blood pressure of 115/80. Furthermore, investigators estimate that the four-year rate of progression from pre-hypertension to hypertension ranges from 25% to 50%.¹⁰ Based on this data, the latest consensus guidelines recommend non-pharmacologic interventions for all persons with “prehypertension” and consideration of pharmacologic therapy for patients with diabetes or kidney disease.¹

Patient awareness and treatment of hypertension is improving, but is far from optimal. In the United States, awareness of hypertension increased from 51% to 70% between 1980 and 2000. Over the same period, treatment increased from 31% to 59%, but blood pressure targets were achieved in only 34% of patients in 2000 (Chobanian *et al.* 2003).

Stress reduction and blood pressure reduction

Prior literature has suggested that stress reduction through non-pharmacologic means, such as yoga or meditation practice, can successfully reduce blood pressure both for normotensive and hypertensive individuals.¹¹⁻¹⁵ However, the studies have often been criticized for poor methodology. Device-guided breathing was developed to isolate one potentially effective part of yoga and meditation practice, focused slow-breathing. It is hypothesized that slow-breathing works by autonomic-regulated peripheral vascular resistance.¹⁶ The RESPeRATE device has a computer which is the size of a common portable tape player, such as a Walkman, and is battery operated; it is attached to a belt with a breathing sensor which goes around the waist, and it has headphones. The device monitors the users’ respiratory pattern, calculates inspiration and expiration times and synthesizes a two-tone melody, with one tone for inhalation and for exhalation. The user synchronizes his/her breathing with the melody, and the device gradually prolongs the exhalation tone, guiding the user to a slower respiratory rate. The goal respiratory rate is <10 breaths per minute with prolonged exhalation. The device automatically stores performance data from each use and is programmed to stop after 15 minutes of use.¹⁷

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

The RESPeRATE device (InterCure LTD, Israel) received FDA 510K clearance on July 2, 2002. The FDA noted the following Indications for Use:

The RESPeRATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words 'device-guided breathing', cross-referenced with the keywords 'hypertension' and 'cardiovascular disease'. The search was performed for the period from 1966 through August 2006. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

There have been seven peer-reviewed published studies of device-guided breathing using the RESPeRATE device to date. One is a recent review of the topic which used a single case report to illustrate the use of the device in practice.¹⁸ Two are small convenience sample studies with pre and post observational designs.^{19, 20} Two are larger prospective studies, the design of which is a little difficult to interpret because they state that they both randomized subjects and matched them based on multiple characteristics.^{21, 22} Because their designs and analyses most closely resemble prospective matched case-control studies, this review classifies them as such. The final two studies are relatively large prospective randomized control trials (RCT).^{23, 24}

TABLE 2. Published Trials on Device-guided Breathing for Hypertension.

Publication	Study Type	Number of Participants
Elliot and Izzo 2006	Case Report	1
Rosenthal et al 2001	Pre-Post Observational Study	13
Viskoper et al 2003	Pre-Post Observational Study	17
Grossman et al 2001	Prospective Matched Case Control	33
Meles et al 2004	Prospective Matched Case Control	79
Schein et al 2001	Randomized Control Trial	65
Elliot et al 2004	Randomized Control Trial	149

Level of Evidence: 1, 3, 5

TA Criterion 2 is met

TA Criterion 3: The technology must improve the net health outcomes.

All of the published studies have examined the effect of device-guided breathing on blood pressure and heart rate (usually in both the home and office). None have directly examined long-term health outcomes, such as cardiovascular disease or stroke rates, in relation to use of the device-guided breathing. However, we do know that high blood pressure is associated with serious adverse health outcomes and that lowering blood pressure is associated with improved health outcomes.¹ Thus, although the studies reviewed did not directly examine health outcomes, it is not unreasonable to assume that improvements in blood pressure are a good surrogate for improvement in health outcomes.

Case-Report and Prospective Observational Studies

The most recent publication is a review and single case report of a 67 year old woman with uncontrolled hypertension, on multiple medications who has chronic obstructive pulmonary disease. The review uses this case to illustrate the use of RESPeRATE to successfully achieve goal blood pressure without addition of another medication.¹⁸ Two other small observational studies enrolled convenience samples of hypertensive patients who were given in-person instruction on the use of the guided-breathing device.^{19, 20} The first of these studies enrolled 13 patients age 25-75 with Stage I or II hypertension, some of whom (n=6) were already being treated with medications but had no dose changes for three weeks prior to the study or during the study, and the remainder of whom were un-medicated.¹⁹ Patients were followed over eight weeks during which they were asked to use the RESPeRATE device 15 minutes per day. There was no control group. Blood pressures were measured at baseline and at the end of the study, both in the office and using 24-ambulatory measurement. Office and ambulatory systolic and diastolic blood pressure were all statistically significantly lower at the end of the study than at baseline (office SBP -7.2 ± 1.9 ; office DBP -3.4 ± 1.6). There was an association between increasing age and decreasing ambulatory systolic blood

pressure. The second of these studies enrolled 17 patients age 40-80 with resistant hypertension, which was defined as SBP 140-160 or DBP 90-100 despite taking \geq three anti-hypertensive medications at maximal dosage.²² Patients with obesity, diabetes, severe chronic conditions, or secondary hypertension were excluded from this study. Patients had no medication changes for three weeks prior to the study or during the study. Patients were followed over eight weeks during which they were asked to use the RESPeRATE device 15 minutes per day in the afternoon and to measure their blood pressure at home in the morning, separate from the treatment session. Office and ambulatory systolic and diastolic blood pressure were all statistically significantly lower at the end of the study than at baseline (office SBP -12.9 ± 11.4 ; office DBP -6.9 ± 6.3). There was no correlation between age, gender, or number of anti-hypertensives on the outcome. Neither study showed any effect of the treatment on heart rate.

Matched Case-Control and Randomized Clinical Trials

The remaining four publications are two case-control studies and two RCTs. All four studies focused on patients with Stage I and II hypertension and had mixed populations in which approximately two-thirds of those enrolled were taking antihypertensive medications and the rest were un-medicated. All of these trials had similar exclusion criteria, which narrowed their enrollees to patients without significant co-morbidities (including ischemic heart disease, history of stroke, renal disease, respiratory diseases, psychiatric disorders); two of the trials did not exclude patients with diabetes mellitus, and they did not report on how many enrollees had diabetes.^{22, 23} Two of the studies had their control group do daily home blood pressure monitoring,^{22, 23} and two studies had their control group do daily home blood pressure monitoring and listen to calm music on a walkman for the same amount of time that the intervention group used the RESPeRATE device.^{21, 24} Three of the four studies taught participants how to use the intervention device in person, while one study gave participants written instructions only.²³ All four studies had similar methodologies for measuring blood pressure from home blood pressure monitors and in the office; all four conducted the intervention and active control for eight weeks. Two studies had participants use the RESPeRATE device for ten minutes per day,^{21, 24} and two studies had participants use the device for 15 minutes per day.^{22, 23} All four studies also precluded participants from changing their medications for a pre-determined time before beginning the intervention (ranging from two weeks to two months) or during the study period. (See Table 3 below)

TABLE 3. Controlled Trials on Device-guided Breathing for Hypertension.

Study	Patient Population	Matching / Randomization and Blinding	Inclusion / Exclusion Criteria	Intervention / Control Group	Endpoint
Grossman et al 2001	33 patients 18 treatment 15 control	Matched on baseline BP, age, gender, medication status. Clinicians blinded to treatment assignment; patients blinded to difference in two groups	Included: age 25-75 uncontrolled office BP (SBP \geq 140 or DBP \geq 90 and home BP >135/85) with or without drug therapy ok; no change in meds x 2 months prior to or during study Excluded: Ischemic heart disease Congestive heart failure Chronic atrial-fibrillation Renal failure Diabetes mellitus Previous stroke Major organ failure Respiratory diseases Psychiatric Disorders Morbid obesity (BMI >35)	Treatment: Use of RESPeRATE device x 10 minutes /day for 8 weeks in PM (patients instructed on use) Daily home BP monitoring AM and PM Control: Use of a walkman playing quiet music x 10 minutes / day for 8 weeks in PM Daily home BP monitoring AM and PM	Clinic Blood Pressure Change in blood pressure from average values of 2 baseline measurements (two-weeks apart) to blood pressure at week 4 and week 8 of treatment Home Blood Pressure Change in blood pressure from baseline (1 week prior to enrollment) and week 8 of treatment Heart Rate Change in heart rate from baseline to week 8 of treatment
Meles et al 2004	79 patients 48 treatment (one dropout) 31 control (five dropouts)	Matched on baseline BP & medication status	Included: age 40-75 uncontrolled office BP (BP > 140/90) with or without drug therapy ok; no change in meds x 2 weeks prior to or during study Excluded: Angina Congestive heart failure Renal failure Cerebrovascular disease Pregnancy Blindness Deafness Inability to use a digital BP monitor	Treatment: Use of RESPeRATE device x 15 minutes /day for 8 weeks in PM (patients instructed on use) Daily home BP monitoring Control: Daily home BP monitoring	Clinic Blood Pressure Change in blood pressure from baseline measurements (two weeks prior to treatment) to blood pressure at end of week 8 of treatment Home Blood Pressure Change in blood pressure from baseline (2 weeks prior to enrollment) and end of week 8 of treatment Heart Rate Change in heart rate from baseline to week 8 of treatment

Schein et al 2001	<p>65 patients 32 treatment (no dropouts) 33 control (four dropouts)</p> <p>43 returned for 6-month follow-up (equal dropout in both groups)</p>	<p>Semi-matched (by baseline MAP, age, gender) pairs randomly assigned to treatment or control group at 3 clinic sites</p> <p>Clinicians blinded to treatment assignment; patients blinded to difference in two groups</p>	<p>Included: age 25-75 uncontrolled office BP (SBP \geq 140 or DBP \geq 90) with or without drug therapy ok; no change in meds x 2 months prior to or during study</p> <p>Excluded: Ischemic heart disease Congestive heart failure Chronic atrial-fibrillation Renal failure Diabetes mellitus Previous stroke Major organ failure Respiratory diseases Psychiatric Disorders Pregnancy Morbid obesity (BMI >35) Inability to operate a portable tape</p>	<p>Treatment: Use of RESPeRATE device x 10 minutes /day for 8 weeks in PM (patients instructed on use) Daily home BP monitoring AM and PM</p> <p>Control: Use of a walkman playing quiet music x 10 minutes / day for 8 weeks in PM Daily home BP monitoring AM and PM</p>	<p>Efficacy predetermined as: Reduction in SBP > 10 Reduction in DBP > 5 Reduction in MAP > 6.7</p> <p>Percent achieving efficacious blood pressure reduction in treatment versus control group.</p> <p>Blood pressure reduction at 6 months after 8-week intervention completed.</p>
Elliot et al 2004	<p>149 patients 29 treatment (non-randomized feasibility pilot)</p> <p>Randomized: 60 treatment 60 control</p> <p>Unclear if dropout and in which group</p>	<p>Randomization 1:1 at 5 clinic sites</p> <p>29 treatment patients were not randomized, but rather enrolled to assess feasibility of self-learning to use RESPeRATE device at home.</p> <p>Remaining randomized patients were blinded to difference in two groups and intent of study to lower BP through slow breathing; clinicians blinded to treatment assignment.</p>	<p>Included: age 40-75 uncontrolled office BP (SBP 140 - 179 and DBP < 110) with or without drug therapy ok; no change in meds x 1 month prior to or during study</p> <p>Excluded: Ischemic heart disease Severe congestive heart failure Chronic atrial-fibrillation Renal failure Previous stroke Major organ failure Respiratory diseases Psychiatric Disorders Pregnancy Morbid obesity (BMI >35) Inability to operate a portable tape</p>	<p>Treatment: Use of RESPeRATE device x 15 minutes /day for 8 weeks in afternoon (patients given written instructions only) Twice daily home BP monitoring</p> <p>Control: Twice daily home BP monitoring plus third home BP monitoring in place of RESPeRATE use.</p>	<p>Significant outcome predetermined as: 6.5 mm Hg difference in SBP between groups</p> <p>Threshold value (minimum duration of use of device) associated with significant outcome.</p>

All four studies showed a positive benefit of use of the RESPeRATE device on office and home blood pressure after eight weeks. (See Table 4 below) Of the two case-controlled studies, one showed a benefit on office SBP and home DBP,²¹ while the other study showed a benefit on office DBP and home SBP.²²

The two RCTs had somewhat different outcome measures. The first, earlier one by Schein et al, found that 78% of the treatment group, compared to 59% of the active control group, achieved a predetermined decrease of 6.7mm Hg in mean arterial pressure; however, this difference was not statistically different.²⁴ The authors did not report a similar statistic for SBP or DBP. In addition, while both groups achieved a decrease in systolic blood pressure, the difference between groups was not statistically significant; whereas, the treatment group achieved a significantly lower diastolic blood pressure than the active control group. Lastly, this study followed participants for six months after the intervention ended, and found a persistently lower systolic and diastolic home blood pressure in the treatment group. However, they were only able to attain follow-up in 66% of the original participants. The second, somewhat larger RCT by Elliott et al, was designed to evaluate a threshold effect of minutes of device use over the treatment period necessary to effect a pre-determined clinically meaningful decrease in systolic blood pressure of 6.8mmg Hg.²³ The study found a threshold of a minimum of 180 minutes over eight weeks to achieve a clinically significant reduction in SBP. However, there was a dose-response which indicated that more use was better, even above the threshold. The authors did not report a threshold of number of sessions per week, which may be a more informative number for clinicians and patients. All groups (intervention low users, intervention high users, and control) experienced a significant decrease in SBP; however, high users (≥ 180 min) had the greatest decrease (15 mm Hg), compared to either low users (7.3 mm Hg) or the control group (9.2 mm Hg).

Table 4. Results of Controlled Trials on Device-guided Breathing.

Study	Adherence to Treatment	Endpoint Results																																
Grossman et al 2001	Personal signed diary of treatment/ active control – 100% One participant non-adherent with home BP measurement	Blood Pressure (mm HG) (adjusted for co-variates) <table border="1"> <thead> <tr> <th></th> <th>Treatment</th> <th>Control</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Clinic SBP</td> <td>-7.5 ± 12.0</td> <td>-2.9 ± 12.1</td> <td>.001</td> </tr> <tr> <td>DBP</td> <td>-4.0 ± 7.7</td> <td>-1.5 ± 9.1</td> <td>.12</td> </tr> <tr> <td>Home SBP</td> <td>-5.0 ± 9.6</td> <td>-1.2 ± 7.3</td> <td>.07</td> </tr> <tr> <td>DBP</td> <td>-2.7 ± 4.9</td> <td>+0.9 ± 3.7</td> <td>.02</td> </tr> </tbody> </table> Heart Rate (beats/min) (adjusted for co-variates) <table border="1"> <thead> <tr> <th></th> <th>Treatment</th> <th>Control</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td>Clinic</td> <td>+0.8 ± 7.8</td> <td>-0.7 ± 9.6</td> <td>.5</td> </tr> <tr> <td>Home</td> <td>-1.0 ± 5.2</td> <td>-0.1 ± 5.0</td> <td>.05</td> </tr> </tbody> </table>		Treatment	Control	p-value	Clinic SBP	-7.5 ± 12.0	-2.9 ± 12.1	.001	DBP	-4.0 ± 7.7	-1.5 ± 9.1	.12	Home SBP	-5.0 ± 9.6	-1.2 ± 7.3	.07	DBP	-2.7 ± 4.9	+0.9 ± 3.7	.02		Treatment	Control	p-value	Clinic	+0.8 ± 7.8	-0.7 ± 9.6	.5	Home	-1.0 ± 5.2	-0.1 ± 5.0	.05
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Elliot et al 2004	96% of treatment group returned the device; 86% of the treatment group used it at least once (n=76) 57% of the treatment group was categorized as 'low users', and the majority did not use the device daily.	Baseline differences: no significant differences between non-randomized and randomized treatment group; no significant differences between treatment and control group Systolic blood pressure reduction at end of 8 weeks (Low users ≤ 180 min; High users ≥ 180 min) <table border="1"> <thead> <tr> <th></th> <th>High users (n=33)</th> <th>Low users (n=43)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td></td> <td>-15.0 ± 1.8</td> <td>-7.3 ± 1.9</td> <td>.005</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th></th> <th>High users (n=33)</th> <th>Control Group (n=60)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td></td> <td>-15.0 ± 1.8</td> <td>-9.2 ± 1.9</td> <td>.012</td> </tr> </tbody> </table>		High users (n=33)	Low users (n=43)	p-value		-15.0 ± 1.8	-7.3 ± 1.9	.005		High users (n=33)	Control Group (n=60)	p-value		-15.0 ± 1.8	-9.2 ± 1.9	.012																
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None of the publications reported any harm resulting from device use. It is feasible that use of the device to attempt to lower blood pressure could delay implementation of an appropriate medication regimen. However, because the impact of hypertension on end-organs accumulates over years, resulting in disease and adverse health outcomes such as coronary heart disease and stroke,^{1, 2} an eight-week trial of device-guided breathing is unlikely to cause significant harm resulting from delays in other available treatments.

TA Criterion 3 is met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The RESPeRATE slow-breathing intervention appears to have an effect in lowering blood pressure approaching that of more intensive changes in diet and sodium intake, as well as exercise. In the Dietary Approaches to Stop Hypertension (DASH) Diet study, participants were asked to follow a low-fat, high fiber, whole-grain diet with varying amounts of sodium intake.^{25, 26} Among patients with Stage I hypertension, lower sodium intake and the DASH diet independently lowered SBP compared to controls (range reduction: -4.9 to -6.6 mm Hg), and the combination of the two had the best results (-11.5 mm Hg). Similarly, in the PREMIER trial, participants were randomized to a minimum intervention advice only group, an established diet/weight loss and exercise group, or a DASH diet and established weight loss and exercise group in an effort to evaluate the impact of lifestyle changes on blood pressure.²⁷ Among patients with Stage I hypertension, both the established and DASH plus established groups had a significant decrease in SBP (-4.6 and -6.3 mm HG respectively), compared to the advice only group, and a significant decrease in DBP (-2.0 and -3.6 mm HG respectively), compared to the advice only group. Thus, the decrease in blood pressure achieved in the RESPeRATE trials is similar to other non-pharmacologic approaches to lowering blood pressure in patients with Stage I hypertension. However, there is no direct data on health outcomes for RESPeRATE; nor is there data to suggest that RESPeRATE has the other potential beneficial effects on health as diet and exercise do.

TA Criterion 4 is met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

Although the majority of the device-guided breathing trials reviewed here conducted in-person instruction on how to use the device, a Google search on the World Wide Web revealed that the RESPeRATE device is widely available for private sale with written instructions. One of the trials (Elliott et al 2004) did test whether participants were able to use the device if given written instructions only, and found that 95% of those who used the device at least once were

able to achieve the target slow breathing of <10 breaths/minute.²³ In all of the studies reviewed, participants used the device on their own in the privacy of their homes and not in the investigational setting. All of the reviewed studies also excluded patients who were unable to operate a walkman. This supports the likelihood that most individuals who could operate a walkman would be able to use this device without difficulty. However, they did not report on the literacy level of their participants or on the use of written instructions across ethnicity or language groups.

TA Criterion 5 is met.

CONCLUSION

All reviewed publications, including two RCTs, of device-guided breathing with the RESPeRATE device to lower blood pressure among patients with Stage I and II hypertension showed moderately positive results. Although there are varying results with regard to SBP and DBP, there is some evidence that it lowers both. Although weaker six month follow-up evidence in one study suggests that the effects of eight weeks of device use may persist even after use has stopped, this data would need repeating in a study designed to follow patients over a longer period of time to be convincing. It appears that perhaps less than daily use of the device can result in improved blood pressure; however, there is a dose response implying that regular daily use may be most beneficial and that there is probably a threshold below which there is no benefit. It also appears that patients can learn to use the device with written instructions only, and can operate it successfully on their own at home; however, it would be useful to test instructions on patients with varying levels of actual and health literacy and in multiple languages to better assess generalizability. Although one small observational trial found good results in patients with resistant hypertension, the RCTs and case-control studies only enrolled healthy individuals with blood pressures in the Stage I and II range. They all included a majority of patients who were already being treated with anti-hypertensive medications. We do not know the ethnicity or literacy levels of patients participating in these trials since these variables are not reported in the publications, but suspect that they were mostly Caucasian and literate, further limiting the generalizability of these results. Despite these limitations, it appears that device-guided breathing is useful for some patients either as primary treatment in Stage I hypertension or as adjunctive treatment for those already taking anti-hypertensive medications with treated blood pressures persisting in the Stage I and II range. It remains unclear if device-guided breathing has a major benefit for SBP, DBP or both. We do not have direct evidence from these trials that lowering blood pressure via this method improves health outcomes; however, it is not unreasonable to make this inference because hypertension itself is such a strong risk factor for adverse health outcomes. Nor do we have good evidence that the achieved blood pressure reduction is sustained over a period of time beyond the eight weeks studied. Nevertheless, extrapolation from numerous studies on pharmacologic therapy of hypertension makes it clearly evident that any (even a small one) reduction in blood pressure reduces the cardiovascular risk of patients.

Further RCTs of device-guided breathing as adjunctive treatment in patients with diabetes mellitus, known ischemic heart disease, prior stroke, and COPD or asthma are needed to understand whether this is a useful treatment in these populations. RCTs comparing and combining device-guided breathing with dietary and exercise treatments would give us more information about their potential additive benefits to these established non-pharmacologic treatments. Lastly, RCTs designed to follow patients longitudinally to examine adherence, minimum necessary number of sessions per week, and long-term effects would add to the clinically useful information about this device.

RECOMMENDATION

It is recommended that daily use of RESPeRATE for device-guided breathing to lower blood pressure either as primary treatment for Stage I hypertension or adjunctive treatment for patients with persistently high blood pressures in the Stage I or II range, and who are otherwise healthy, non-pregnant, individuals meets CTAF criteria 1-5 for safety, effectiveness and improvement in health outcomes.

October 18, 2006

The CTAF panel voted unanimously in favor of this modified recommendation:

It is recommended that daily use of RESPeRATE for device-guided breathing to lower systolic blood pressure as adjunctive treatment for patients with persistently high blood pressure in the Stage I or II range, and who are otherwise healthy, non-pregnant individuals, meets CTAF Technology Assessment Criteria 1 through 5 for safety, effectiveness and improvement in health outcomes.

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

Centers for Medicare and Medicaid Services (CMS)

At this time there is not published policy regarding the use of this technology.

American College of Cardiology – California Chapter (CA ACC)

The CA ACC does not have an opinion on this technology.

American Society of Hypertension (ASH)

ASH has been invited to provide an opinion on this technology and to have representation at the meeting.

ABBREVIATIONS USED IN THIS ASSESSMENT:

CHD: Coronary heart disease

SBP: Systolic blood pressure

DBP: Diastolic blood pressure

JNC: Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood pressure

DARE: Database of Abstracts of Reviews of Effects

RCT: Randomized control trials

DASH: Dietary Approaches to Stop Hypertension

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