

Resperate® for hypertension

Background and Introduction

This is a newsletter designed to provide information about new medical devices that enter the healthcare market that are prescribable on FP10. Information on new devices is often hard to get, independent evaluations may be scarce and devices may be expensive. There may also be a patient demand driven by interest groups.

Device name and manufacturer

Resperate ("RESPeRATE") is marketed by Intercure Ltd based in Israel, with offices in London, Canada and USA.

What is the Technology

This electronic device uses device-guided breathing to reduce blood pressure.¹ It produces musical tones that encourage a reduction in breathing rate (particularly exhalation rate), which after some training produces a decrease in blood pressure. It is thought to utilise a physiological mechanism that decreases sympathetic nervous system activity and sensitises arterial and cardiopulmonary baroreceptors, resulting in an increase in parasympathetic activity and consequent reduction of blood pressure. According to the manufacturer, respiratory rate needs to be decreased to 10 breaths/minute to be effective at lowering blood pressure. Use of the device is advised for 15 minutes a day, it is suggested that reduction in blood pressure is related to time spent on slow breathing.² The rechargeable electronic device is accompanied by ear phones and a waist band that is used to detect respiratory rate.¹

What is the evidence for effectiveness of the device?

A systematic review of studies with the device was published in 2012.³ The authors located eight studies with 494 hypertensive patients from 3 countries. Seven studies compared the Resperate with another electronic musical device or standard BP monitoring unit, one study compared the device with 'usual care'. The length of trials varied between 4 and 9 weeks. Meta-analysis of the results found a small decrease in systolic and diastolic BP: change in systolic BP was -2.46mm Hg (95% CI -4.74 to -0.18, P=0.03) and diastolic BP -2.22mmHg (95% CI -3.74 to -0.66, P=0.005). There was no overall effect on resting heart rate. Blinding in the trials was not possible, so the authors of the meta-analysis carried out a sensitivity analysis which excluded all trials sponsored by the manufacturer. This left three trials with a total of 100 patients. Meta-analysis of this data found no significant effect on either systolic or diastolic blood pressure. The authors conclude that longer term independent trials of the device are needed to investigate this intervention further.

No long term data is available on efficacy of the device on outcomes for people who use the device instead of conventional therapy. There is no data for patients who do not continually use the device for 15 minutes daily.

The British Hypertension Society (BHS) commented in April 2012 that: *'In the opinion of the BHS, such small effects (on blood pressure, heart rate and quality of life) over very short durations of time do not provide sufficient evidence for this equipment to be recommended.'*⁴

An NHS Evidence update (March 2013) concluded that further research was desirable and that *'the available evidence does not seem to support the use of this device for the treatment of hypertension and is not likely to influence the recommendations in NICE CG127'*.

Costs

Drug Tariff price for the device (May 2013) is £132.00. It is unclear how long a device would last, but it would probably need to be replaced if dropped accidentally. The retail price is higher – the manufacturer's website quotes cost ranging from £203.95 to £349.95 including VAT, depending on model.

References

1. Manufacturers website for Resperate at www.resperate.co.uk, accessed 7/5/13
2. Elliott W et al. Non-Drug Blood Pressure-Lowering Device: A Clinical Overview. http://www.resperate.co.uk/media/pdfs/downloadable_mail_package.pdf, accessed 7/5/13
3. Mahtani K et al. Device-guided breathing exercises in the control of human blood pressure: systematic review and meta-analysis. *J Hypertens* 2012; 30:852–860.
4. BHS statement, at <http://www.bhsoc.org/pdfs/Statement%20on%20RESPeRATE%20April%202012.pdf>, accessed 7.5.13
5. NHS Evidence update March 2013 at <http://www.evidence.nhs.uk/evidence-update-32> accessed 7/5/13