

# Biofeedback Lowers Blood Pressure in Type 2 Patients

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COPENHAGEN — Self-treatment with a biofeedback device that guides breathing can significantly lower blood pressure among patients with type 2 diabetes. Dr. Moshe H. Schein reported at the annual meeting of the European Association for the Study of Diabetes.

The device, called RESPeRATE, is made by InterCure Ltd., Lod, Israel. It was approved by the U.S. Food and Drug Administration in 2002 for use in stress reduction and as adjunctive treatment for hypertension, together with other pharmacologic and nonpharmacologic interventions. It works by using melodic tones to guide the patient through progressively slower inhalation and exhalation.

Previous data have shown that the device-guided technique results in significant blood pressure reductions among hyper-

**Systolic blood pressure dipped by 9.5 mm Hg in patients in the device group, compared with an increase of 2.1 mm Hg in those in the control group.**

tensive patients who use it at home on a daily basis (J. Hum. Hypertens. 2001;15:271-8).

In the new study, a total of 60 patients with type 2 diabetes who had blood pressures greater than 130/80 mm Hg were randomized to use of the device for 15 minutes a day along with usual treatment, or to usual treatment alone for 8 weeks. The group was 60% male, with a mean age of 64 years and a mean body mass index of 30 kg/m<sup>2</sup>.

At baseline, mean blood pressure was 149/82 mm Hg in the treatment group and 146/81 mm Hg in the control group, even though the majority—78% of the treatment group and 89% of the controls—were taking blood pressure medication, said Dr. Schein, director of the Family Medicine Unit, Hadassah University Hospital, Jerusalem.

Systolic blood pressure dropped by 9.5 mm Hg in the group using the device, compared with an increase of 2.1 mm Hg among the controls, a significant difference between the two groups. The change in pulse pressure also was significantly different at 2 months; it dropped by 5.9 mm Hg from a mean of 67 mm Hg at baseline in the guided-breathing group, and increased by 3.6 mm Hg from a mean of 66 mm Hg in the controls.

Diastolic blood pressure dropped slightly in both groups, by 3.5 mm Hg in the guided-breathing patients and by 1.5 mm Hg among the controls. That difference was not significant.

There was a dose-response relationship between use of the device and systolic blood pressure reduction: The longer the patient spent in the slow breathing exercise, the greater the drop. (Although patients had

been instructed to perform the device-guided breathing exercise daily, they actually did it for a mean of 5.6 sessions per week. However, each session lasted 15.9 minutes, slightly longer than the instructed 15 minutes, and patients spent a mean of 40.4 minutes per week in slow breathing. Blood pressure control, defined as 130/80 mm Hg or below, was achieved by 8 of 30 (27%) in the device group, compared with 2 of the 30 (7%) controls. ■



The RESPeRATE device uses melodic tones to progressively slow the patient's breathing, which results in significant blood pressure reductions among hypertensive patients who use it at home on a daily basis.

INTERCURE LTD.

Newly published data vs rosuvastatin

As an adjunct to diet when diet alone is not

## What mean LDL-C reduction did and rosuvastatin did not?

- ▶ VYTORIN 10/40 mg was superior to atorvastatin 40 mg at lowering LDL-C (57% vs 48%,  $P < 0.001$ ).<sup>1</sup>
- ▶ VYTORIN 10/40 mg and 10/80 mg were both superior to atorvastatin 80 mg at lowering LDL-C (57% and 59% vs 53%, respectively,  $P < 0.001$ ).<sup>1</sup>

\*Mean percent change in LDL-C from untreated baseline in a multicenter, double-blind, randomized, active-controlled, 8-arm, parallel-group study (6 weeks of active treatment) (N=1,902). Patients with hypercholesterolemia who had not met their LDL-C goal as defined by NCEP ATP III were randomized to VYTORIN 10/10, 10/20, 10/40, or 10/80 mg or atorvastatin 10, 20, 40, or 80 mg. Mean pooled baseline LDL-C values for VYTORIN and atorvastatin were 178 mg/dL and 179 mg/dL, respectively. VYTORIN 10/10 mg reduced LDL-C by 47% from baseline vs 36% with atorvastatin 10 mg ( $P < 0.001$ ).<sup>1</sup>

- ▶ The dosage should be individualized according to baseline LDL-C level, the recommended goal of therapy, and the patient's response.

**VYTORIN is indicated as adjunctive therapy to diet** for the reduction of elevated TOTAL-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipidemia when diet alone is not enough.

**Contraindications:** hypersensitivity to any component of this medication; active liver disease; unexplained persistent elevations of serum transaminases; and women who are pregnant, nursing, or may become pregnant.

VYTORIN contains 2 active ingredients: ezetimibe and simvastatin.

No incremental benefit of VYTORIN on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.

The clinical impact of comparative differences in lipid changes between products is not known.

### SELECTED CAUTIONARY INFORMATION

**Skeletal Muscle:** Myopathy sometimes takes the form of rhabdomyolysis with or without acute renal failure secondary to myoglobinuria, and rare fatalities have occurred. The risk of myopathy/rhabdomyolysis is dose related. Tell patients to promptly report muscle pain, tenderness, or weakness. Discontinue drug if myopathy is suspected or CPK levels rise markedly.

**Myopathy Caused by Drug Interactions:** Use of VYTORIN with itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, nefazodone, or large quantities of grapefruit juice (>1 quart daily) should be avoided because of the increased risk of myopathy, particularly at higher doses.

### VYTORIN vs atorvastatin<sup>1</sup>

Significantly greater LDL-C reduction\*

