

Study Raises the Bar for Maintaining Weight Loss

BY MARY ANN MOON
Contributing Writer

Women who lose 10% or more of their body weight through diet and exercise must engage in 275 minutes per week of physical activity to maintain that weight loss beyond the initial 6 months, according to a report.

The level of physical activity needed to sustain weight loss over the long term "is about twice the public health recommen-

ation" of 30 minutes of moderate-intensity activity on most days of the week, said Dr. John M. Jakicic of the University of Pittsburgh's Physical Activity and Weight Management Research Center and his associates.

They studied the effect of exercise on weight loss in 191 overweight women who participated in a 2-year intervention. They were aged 21-45 years, were sedentary, and had a body mass index of 27-40 kg/m².

The women were prescribed a 1,500-calorie per day diet and were assigned to

one of four levels of exercise. They attended weekly group meetings focused on strategies for modifying eating and exercise behaviors for the first 6 months of the intervention and monthly meetings thereafter. They also received brief periodic phone calls from the intervention team for support and encouragement.

A total of 170 subjects (89%) completed the full 2 years of the intervention. Weight loss and regain was similar across all categories of exercise intensity and duration.

As a group, they lost a mean of 8 kg by 6-month follow-up, then gradually regained about half of that amount so that the mean weight loss totaled 4.2 kg at 2 years.

Exercise followed the same pattern as weight fluctuation, increasing for the first 6 months of intervention and gradually decreasing over time. "The inability to sustain weight loss appears to mirror the inability to sustain physical activity," said the authors (Arch. Intern. Med. 2008;168:1550-9).

Subjects who achieved and maintained a weight loss of 10% or more of their initial body weight—only 25% of the total—engaged in at least 1,800 kcal/wk of physical activity, which corresponds to 275 minutes



Women need 275 minutes of exercise a week to maintain their weight loss.

a week above their baseline level of activity. The findings clarify the amount of physical activity necessary to achieve and sustain weight loss and demonstrate the difficulty women have in sustaining this level of activity, the authors added. ■

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INDICATIONS AND USAGE

PATADAY™ solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

CONTRAINDICATIONS

Hypersensitivity to any components of this product.

WARNINGS

For topical ocular use only. Not for injection or oral use.

PRECAUTIONS

Information for Patients

As with any eye drop, to prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. Patients should be advised not to wear a contact lens if their eye is red.

PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation. The preservative in PATADAY™ solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red, should be instructed to wait at least ten minutes after instilling PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% before they insert their contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

Pregnancy:

Teratogenic effects: Pregnancy Category C

Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers:

Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% is administered to a nursing mother.

Pediatric Use:

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

Geriatric Use:

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

The following adverse experiences have been reported in 5% or less of patients:

Ocular: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus.

Non-ocular: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion. Some of these events were similar to the underlying disease being studied.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop in each affected eye once a day.

HOW SUPPLIED

PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% is supplied in a white, oval, low density polyethylene DROP-TAINER® dispenser with a natural low density polyethylene dispensing plug and a white polypropylene cap. Tamper evidence is provided with a shrink band around the closure and neck area of the package.

NDC 0065-0272-25

2.5 mL fill in 4 mL oval bottle

Storage:

Store at 2°C to 25°C (36°F to 77°F)

U.S. Patents Nos. 4,871,865; 4,923,892; 5,116,863; 5,641,805; 6,995,186

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References:

- Vogelsohn CT, Abelson MB, Pasquine T, et al. Preclinical and clinical antiallergic effect of olopatadine 0.2% solution 24 hours after topical ocular administration. *Allergy Asthma Proc.* 2004;25:69-75.
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Encourage Moderate Aerobic Fitness in African Americans

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NEW ORLEANS — Moderate aerobic fitness has a significant beneficial effect on various components of metabolic syndrome in nondiabetic overweight or obese African American women.

In 68 African American women with a mean age of 47 years and a mean body mass index of 33.6 kg/m², moderate aerobic fitness levels were associated with significantly lower BMI, waist circumference, and insulin resistance, compared with low and very low aerobic fitness levels.

The overall prevalence of metabolic syndrome was 25%, with the 29 women with moderate aerobic fitness having the lowest prevalence (14%), compared with the 14 women with low aerobic fitness (29%) and the 25 women with very low aerobic fitness (32%), Trudy Gaillard, Ph.D, R.N., said at a meeting sponsored by the International Society on Hypertension in Blacks.

In addition, the percentage of women in the study with a waist circumference meeting Adult Treatment Panel III (ATP III) criteria for metabolic syndrome was 31% in the moderate fitness group, compared with 84% and 64% in the low and very low fitness groups, respectively, said Dr. Gaillard of the Ohio State University Medical Center, Columbus.

The percentages meeting the high-density lipoprotein cholesterol ATP III criteria for metabolic syndrome were 46% in the moderate fitness group, and 57% and 60% in the low and very low fitness groups, and the percentages meeting the systolic blood pressure ATP III criteria for metabolic syndrome were 7% in the mod-

erate fitness group, and 36% and 21% in the low and very low fitness groups.

The prevalence of metabolic syndrome and the individual components of the syndrome varied by aerobic fitness level for all components of metabolic syndrome except serum glucose and triglycerides.

Assessments were made using fasting and 2-hour postprandial serum glucose, insulin, and C-peptide levels obtained during an oral glucose tolerance test. Insulin resistance was measured by the homeostasis assessment model, and aerobic fitness was empirically categorized based on VO₂ max, with VO₂ max less than 21 mL/kg per minute considered very low aerobic fitness; VO₂ max between 21 and 24.4 mL/kg per minute, low aerobic fitness; and VO₂ max greater than 24.4 mL/kg per minute, moderate aerobic fitness. Moderate aerobic fitness is roughly the equivalent of brisk walking for 30 minutes a day, Dr. Gaillard said.

Findings from other studies link reduced levels of physical fitness and increased levels of sedentary activity to increased risk of metabolic syndrome. Still other studies suggest a sedentary lifestyle doubles the risk of cardiovascular disease, and that an active lifestyle halves the risk of hypertension.

African American women have been shown in studies to have the highest levels of inactivity. They also expend less energy during exercise, regardless of weight, suggesting that more exercise is needed to achieve the same benefits seen at lower levels in other populations, Dr. Gaillard noted, adding that health care providers should encourage moderate physical activity in all African American women, regardless of their level of obesity, physical activity, or risk for comorbidities. ■