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The full report is titled “Effects of Sibutramine Treatment in Obese Adolescents. A Randomized Trial.” It is in the 18 July 2006 issue of *Annals of Internal Medicine* (volume 145, pages 81-90). The authors are R.I. Berkowitz, K. Fujioka, S.R. Daniels, A.G. Hoppin, S. Owen, A.C. Perry, M.S. Sothorn, C.L. Renz, M.A. Pirner, J.K. Walch, O. Jasinsky, A.C. Hewkin, and V.A. Blakesley, for the Sibutramine Adolescent Study Group.

Effects of Drug Treatment for Obesity in Adolescence

What is the problem and what is known about it so far?

Being obese during adolescence is an increasing problem in the United States; 15% of adolescents are obese. Obesity is a serious problem. It increases the likelihood of having diabetes or heart disease later in life and of dying while still in middle age. Adolescents who are obese are more likely to be depressed or to feel unpopular with schoolmates. Adolescents have trouble losing weight and keeping it off. In a clinical trial in obese adolescents, sibutramine caused weight loss, but the study lasted only 6 months.

Why did the researchers do this particular study?

To see whether sibutramine reduces weight more than placebo in obese adolescents who are receiving counseling to help them exercise more and reduce the amount of food that they eat.

Who was studied?

498 obese adolescent boys and girls 12 to 16 years of age.

How was the study done?

The researchers randomly assigned 368 participants to receive sibutramine (10 mg) and 130 participants to receive placebo (sugar pill) once a day for 1 year. All participants regularly received counseling about how to eat less food, increase physical activity, reduce stress, and keep track of how much they ate. The researchers then measured weight, blood pressure, and pulse rate every month.

What did the researchers find?

The average weight of participants before the study was 215 pounds. Adolescents who took sibutramine usually lost weight (about 14 pounds), while those who took placebo usually gained weight (about 4 pounds). At 1 year, the average difference in weight between groups was 18.5 pounds. Participants who took sibutramine on average lost weight rapidly during the first 8 months and then maintained weight until 1 year. They also gained height and matured sexually at the same rate as those who took placebo. The main drug side effect was rapid heart rate, which occurred in 12.5% of participants receiving sibutramine and 6.2% of participants who took placebo. The number of participants who stopped taking their study pills because of side effects was similar in both groups.

What were the limitations of the study?

The study lasted only 1 year, which is not long enough to measure the long-term benefits or harms of sibutramine in adolescents. It did not measure changes in weight after stopping sibutramine treatment. About one quarter of the participants did not complete the study.

What are the implications of the study?

In obese adolescents who were getting counseling to lose weight, taking sibutramine reduced weight and did not affect physical maturation.

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