ABSTRACT

Approximately 60% of the population in the United States is overweight or obese; the prevalence of this condition has risen sharply in recent years and continues to rise. An increase in weight-related comorbid conditions, such as coronary heart disease, diabetes, breast and colon cancer, and osteoarthritis, as well as an increase in health care costs, has accompanied the increase in America’s weight gain. The considerable degree of morbidity and mortality and the increasing recognition of the physiologic factors that regulate appetite have prompted the development and application of a medical model to treat obesity as a disease while considering the closely linked emotional issues and behavioral patterns frequently seen in obese persons. A number of treatment modalities are available, including weight-loss groups, prescribed food plans, meal-replacement plans, other special diets, exercise programs and equipment, and 2 relatively new pharmacologic agents.

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OBESITY AS AN EPIDEMIC

With approximately 60% of the total population in the United States classified as overweight or obese, and with excess weight strongly associated with comorbid conditions such as coronary heart disease (CHD), type 2 diabetes, hypertension, breast and colon cancer, and sleep apnea, the statement that obesity is killing America would not be overly dramatic. In fact, approximately 280,000 adult deaths in the United States each year are attributed to obesity.

CHD alone, which affects an estimated 12.4 million Americans, remains the nation’s leading cause of death. For those who survive a myocardial infarction or live with angina or other manifestations of CHD every day, the adverse impact on quality of life is considerable. For these individuals who have obesity and related comorbid conditions, the morbidity and mortality resulting from the combination of conditions clearly indicates that maintaining an appropriate weight is a major public health issue, not simply a behavioral problem that results from losing control and overeating.

Obesity as an Epidemic

The reality of the situation is that obesity has reached epidemic proportions. As statistics from the Centers for Disease Control and Prevention indicate, the prevalence of obesity has been rising steadily in recent years and continues to rise. Of particular concern is that the increased prevalence is not confined to adults, who represent the largest segment of overweight individuals, but is seen in children and adoles-
cents as well. This sets the stage for an even larger upswing in the prevalence of obesity in adults in the decades to come. For example, for the years 1989 to 1994, 55% of adults who were 20 years of age or older were overweight, as were 11% of adolescents between the ages of 12 and 17 and 14% of children between the ages of 6 and 11. For both children and adolescents, those statistics reflect an increase of 6% from the years 1976 to 1980.1

**Body Mass Index**

To derive prevalence, morbidity, and mortality data, most health organizations and published information on excess body weight and its associated risk factors use the body mass index (BMI) to measure and define overweight and obesity. While BMI does not directly measure the percentage of body fat, it does provide a more accurate measure of overweight and obesity than relying on weight alone.

BMI is calculated by multiplying the weight in pounds by 704.5, dividing the result by the height in inches, and dividing that result by the height in inches a second time. Thus, a woman who is 5’4” tall and weighs 163 pounds has a BMI of 28 (163 X 704.5 = 114833.5 ÷ 64 = 1794.3 ÷ 64 = 28). The National Institutes of Health (NIH) and many other health organizations use 704.5 as the multiplier in calculating BMI. The American Dietetic Association suggests using 700 as the multiplier. The difference in the calculated result is only a few tenths and is insignificant.

The NIH defines overweight as a BMI of 25 to 29.9 and obesity as a BMI of 30 or higher.5,6 Defining overweight as a BMI of 25 or higher is consistent with the recommendations of the World Health Organization7 as well as those of most other countries.

Other methods to determine whether a person is overweight or obese include weight-for-height charts, measurements of body fat (eg, skinfold thickness measurements, bioelectrical impedance analysis), and measurement of waist circumference. Just as health risks increase with increasing BMI, studies have shown that they also increase with increasing waist circumference. Women with waists measuring more than 35 inches and men with waists measuring more than 40 inches may be at a particularly increased risk for developing heart disease, diabetes, hypertension, gallbladder disease, stroke, and certain cancers.8,9

Of the 97 million adults ages 20 years and older who have a BMI of 25 or higher (55% of the total population), 47 million are women and 50 million are men. Of these 97 million adults, nearly 40 million (22.3% of the population) have a BMI of 30 or higher; 23 million are women and nearly 17 million are men. Thus, less than half of all adults in this country (73 million, or 41.4% of the total population) are at a healthy weight, with a BMI between 19 and 25. Of these 73 million adults, 40 million are women and 33 million are men.5 About 3.6% of Americans are underweight, with a BMI of less than 19.1

**Comorbidity Conditions and Health Risks**

The prevalence of obesity and overweight in racial or ethnic minorities, especially minority women, is generally higher than in white individuals (Table 1).5,10 Prevalence rates are also high in persons with diabetes: 67% in those with a BMI of 27 or higher and 46% in those with a BMI of 30 or higher.1 The high prevalence in persons with diabetes is particularly significant as the relative risk for the disease increases in women by approximately 25% with each additional BMI unit over 22.11 In addition, the prevalence of comorbid conditions such as hypertension and hypercholesterolemia increases in those who are overweight or obese (Table 2).5,12

Considerable evidence indicates that health risks increase significantly in persons with a BMI of 25 or higher. From a public health standpoint, this information causes particular concern, primarily because numerous studies have shown that the number of persons in the United States with a BMI of 25 or above continues to rise steadily for individuals of all racial and ethnic groups and adults of all age groups until the 7th decade (60 to 69 years of age), with the exception of white men in their 20s to 40s.15 Between 1960 and 1994, the prevalence of overweight adults (BMI of 25 to 29.9) rose from 31.6% to 32.6%. The prevalence of obesity (BMI of 30 or above) during this same interval increased from 13.4% to 22.3%, a relative increase of more than 50%, with most of the rise seen in the last decade.10 More recent data, covering the years 1991 to 1998, indicate that the prevalence of obesity increased in every state in this country, in both men and women, in smokers and nonsmokers, and across all racial and ethnic groups, age groups, and educational levels.13

Although direct prevalence data are not available, several studies have found that heavier persons are at
increased risk for endometrial cancer, colorectal cancer, gallbladder cancer, and renal cell cancer. Another study reported a link between excess body weight and breast cancer, finding that nearly half of the post-menopausal women diagnosed with breast cancer have a BMI of 29 or higher. The large-scale Nurses Health Study found that women who gained more than 20 pounds from age 18 to mid-life doubled their risk of breast cancer compared with women whose weight remained stable.

To summarize, overweight and obesity, as defined by BMI, are known risk factors for heart disease, stroke, diabetes, hypertension, gallbladder disease, osteoarthritis, sleep apnea, and cancer of the breast, endometrium, colon and rectum, kidney, and gallbladder. Obesity is associated with hypercholesterolemia, complications of pregnancy, menstrual irregularities, hirsutism, stress incontinence, psychological disorders such as depression, and increased surgical risk.

In addition to its considerable contribution to morbidity, obesity is associated with increased mortality. Most studies have found that obese individuals with a BMI of 30 or higher have a 50% to 100% increased risk of death from all causes compared with persons of normal weight (BMI between 20 and 25). Most of the increased risk is attributable to cardiovascular causes.

Being overweight or obese most frequently results from a combination of excessive caloric intake and insufficient physical activity. Efforts to curb the epidemic must address proper diet, behavioral issues related to overeating, and physical activity. Unfortunately, only 22% of adults in the United States get the recommended amount of regular physical activity of any intensity (5 times a week for at least 30 minutes each time) during leisure time and only 15% engage in the recommended amount of vigorous activity (3 times a week for at least 20 minutes each time). Roughly 25% of adults claim they engage in no physical activity at all in their leisure time.

The situation is only slightly better among young people between 12 and 21 years of age. About 15% of young people engage in light to moderate activity such as walking or bicycling nearly every day, and about 50% regularly engage in vigorous physical activity. However,

### Table 1. Prevalence of Obesity and Overweight in Racial/Ethnic Minorities and Caucasians in the United States*

<table>
<thead>
<tr>
<th>Racial/Ethnic Group</th>
<th>BMI ≥ 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American women</td>
<td>65.8%</td>
</tr>
<tr>
<td>African American men</td>
<td>56.5%</td>
</tr>
<tr>
<td>Mexican American women</td>
<td>65.9%</td>
</tr>
<tr>
<td>Mexican American men</td>
<td>63.9%</td>
</tr>
<tr>
<td>Caucasian women</td>
<td>49.2%</td>
</tr>
<tr>
<td>Caucasian men</td>
<td>61.0%</td>
</tr>
</tbody>
</table>


### Table 2. Prevalence of Hypertension and Hypercholesterolemia in Normal Weight, Overweight, and Obese Americans

<table>
<thead>
<tr>
<th>Comorbid Condition</th>
<th>BMI &lt;25</th>
<th>BMI ≥ 25 and &lt; 30</th>
<th>BMI ≥ 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension*</td>
<td>18.2%</td>
<td>23.9% (men)</td>
<td>38.4% (men)</td>
</tr>
<tr>
<td></td>
<td>16.5%</td>
<td>23% (women)</td>
<td>32.2% (women)</td>
</tr>
<tr>
<td>Hypercholesterolemia†</td>
<td>19.7%</td>
<td>19% (men)</td>
<td>20.2% (men)</td>
</tr>
<tr>
<td></td>
<td>15.7%</td>
<td>28% (women)</td>
<td>24.7% (women)</td>
</tr>
</tbody>
</table>

* ≥140/90 mm Hg or currently taking antihypertensive medication.
† ≥ 240 mg/dL.

25% report no vigorous physical activity and 14% report no recent vigorous or light to moderate activity.\textsuperscript{18}

**Economic Cost**

In addition to the rising prevalence of adults, adolescents, and children who are overweight or obese, another index that confirms the presence of an epidemic is economic cost. The total costs associated with obesity and overweight are staggering: $99.2 billion, with $51.6 billion—or 5.7% of total health care expenditures in the United States—in direct health care costs for preventive, diagnostic, and treatment services, and $47.6 billion in indirect costs, such as time lost from work because of illness or disability and future earnings lost because of premature death. A particular point worth noting is that the indirect costs associated with being overweight or obese are comparable to those associated with cigarette smoking.\textsuperscript{18}

The costs of overweight and obesity in several related comorbid conditions are shown in Table 3. They represent the economic costs incurred in this country in 1995 according to researchers who based their data on existing epidemiologic studies that defined obesity as a BMI of 29 or higher.\textsuperscript{19}

In addition to the direct health care costs associated with obesity and overweight and associated comorbid conditions, Americans spend approximately $33 billion annually on weight-loss products and services. These represent all efforts at weight loss and maintenance, including low-calorie foods, artificially sweetened products, and enrollment in commercial weight-loss centers.\textsuperscript{19}

Clearly, obesity and overweight represent an epidemic that will require action on several fronts before it is curbed. To explore what actions might be most appropriate, and to identify the most effective treatments to help patients lose weight and keep it off, several experts in obesity research and weight-loss management shared their thoughts on these subjects. Their suggestions and the discussions that these suggestions generated are summarized in the sections that follow. Where appropriate, clinical trial data and observations based on years of clinical experience are cited.

**A Medical Problem with Behavioral Components**

Being obese is a major risk factor for many medical disorders. As such, many experts in obesity research and management have recommended that obesity be treated medically, as any other medical conditions would be treated. Obesity should not be considered a character weakness, and should not be thought of as the result of being out of control, having a lack of willpower, or as the behavioral consequence of eating too much or exercising too little. People with excess weight have heard these so-called reasons too many times, and many are justifiably offended. However, many emotional and behavioral issues are intertwined with the complex physiologic factors that regulate appetite and underlie energy expenditure, and these should not be ignored.

Application of a medical model to the treatment of obesity begins with the recognition that obesity is a health problem, not a social problem. It is a health

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**Table 3. Costs of Overweight and Obesity by Selected Comorbid Conditions**

<table>
<thead>
<tr>
<th>Comorbid Condition</th>
<th>Direct Cost</th>
<th>Indirect Cost</th>
<th>Total Cost of Condition</th>
<th>% Attributable to Excess Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>$6.99 billion</td>
<td>$33.41 billion</td>
<td>$40.4 billion*</td>
<td>17*</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>$32.4 billion</td>
<td>$30.74 billion</td>
<td>$63.14 billion</td>
<td>&gt;60%</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>$4.3 billion</td>
<td>$12.9 billion</td>
<td>$17.2 billion</td>
<td>-</td>
</tr>
<tr>
<td>Hypertension</td>
<td>$3.23 billion</td>
<td>$15.77 billion</td>
<td>$19 billion</td>
<td>17%</td>
</tr>
<tr>
<td>Breast cancer*</td>
<td>$840 million</td>
<td>$1.48 billion</td>
<td>$2.32 billion</td>
<td>-</td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>$286 million</td>
<td>$504 million</td>
<td>$790 million</td>
<td>-</td>
</tr>
<tr>
<td>Colon cancer</td>
<td>$1 billion</td>
<td>$1.78 billion</td>
<td>$2.78 billion</td>
<td>-</td>
</tr>
</tbody>
</table>

\* Independent of stroke.
\* Postmenopausal.

problem that requires treatment and in most cases it is a lifelong, or at least long-term, condition, not an acute event. As a lifelong condition, it generally requires lifelong treatment and ongoing support and follow-up, just as hypertension and diabetes do. And as a lifelong condition associated with considerable morbidity and mortality, it requires that effective weight-loss strategies, weight maintenance programs, and approaches to prevention be available and in place, and it requires the participation of all physicians and health care professionals, not just those who specialize in obesity management.

At present, several effective treatment strategies are available for long-term weight loss. Although they vary in their success rates, all require some degree of ongoing support and follow-up. As with the treatment of other chronic conditions, compliance with therapy is an issue.

The physiologic principles of weight gain and weight loss can be stated quite simply. Weight is a function of the relationship between caloric intake and caloric expenditure. When intake exceeds expenditure, weight is gained. Conversely, when expenditure exceeds intake, as occurs with a calorie-restricted diet or increased physical activity, weight is lost. Why, then, is losing weight and keeping it off so difficult?

As experts in obesity management are learning every day, through research and through encounters with patients who know they need to or are actually trying to lose weight, being overweight or obese not only results from a physiologic imbalance between caloric intake and expenditure, but also carries a deeply rooted set of emotional issues. These issues, as well as issues related to inadequate knowledge of nutrition, exercise, health risks, and goal setting, are the cause of the derailment of many weight-loss programs, no matter how effective the program was in clinical trials or real life, and no matter how motivated the patient claims to be.

Among overweight and obese individuals, many of the same reasons or rationalizations for not being able to maintain healthy weight are repeated when discussing weight loss. Frequently repeated reasons include eating as a response to stress, for comfort, or because of a sense of obligation, such as for business dinners. Some individuals who are overweight mistakenly assume that weight gain is a natural part of aging, so they believe that losing weight would simply be too difficult or counter to nature’s intent. Others individuals can manage dietary issues but claim they do not have time to exercise, do not know how to exercise properly, or think that they cannot exercise because they have any number of physical ailments. Some individuals who have been overweight for all or most of their lives and have failed in previous attempts to lose weight have given up on trying again because they are discouraged by their failures. Others only want to lose weight for a specific event, such as a wedding or even to please a mate; they may reach their goal, but have difficulty maintaining it because of the methods they may have used for temporary, rapid weight loss and because their motivation is inappropriate. Still others are too tempted by advertisements to resist rich, fattening, or unhealthy foods, or they feel deprived when friends or family members eat such foods and they cannot.

Clearly, for any weight-loss program to succeed it must recognize and address not only the physiologic and nutritional aspects of diet and exercise, but the emotional and behavioral issues as well. Patients need sound advice and accurate information about proper nutrition, balanced diets, appropriate exercise, realistic goal setting, and the health advantages of losing weight. They also need motivation, encouragement, and ongoing follow-up and support. Therefore, many experts recommend that when physicians and other health care professionals advise patients to lose weight they do so through the emotional window, with compassion and with an understanding of why the patient is overweight and why he or she has failed at previous weight-loss attempts.

**Treatment Strategies**

Many treatment strategies are available to help patients lose weight. Most are diet- or diet and exercise-based, many are fairly successful in the short run and some in the long run, and some—notably crash diets and fad diets—are undertaken by patients without, or against, medical advice or supervision. Each strategy has pros and cons. No single approach is appropriate for everyone. In addition, patients and physicians should keep in mind that an approach that was suitable for a specific patient 2 years ago may not be suitable for the same patient now or 2 years from now.

Treatment strategies include weight-loss groups such as Weight Watchers, Overeaters Anonymous, and Take Off Pounds Sensibly; prescribed food plans such as Jenny Craig and Nutri-System; meal-replacement
plans such as Slim-Fast and Opti-Fast; a broad range of diets and diet and exercise programs; numerous exercise programs and equipment; various pharmacologic agents; and, in selected patients, gastric bypass surgery.20

**Patient Feedback**

For patients who need to lose weight, have attempted to lose weight, are currently on a weight-loss program, or plan to start a weight-loss program, focus groups and one-on-one interviews have revealed some valuable insights into why some programs and patients are successful while others are not.21 Typical comments by patients who are not successful at losing weight include disappointment with the weight-loss group or method or inability to identify with others in the group. Some are unable to maintain weight loss from previous diet attempts, often because of the method used, such as commercial liquid diets or simply an overly restrictive diet that cannot be reasonably maintained. Others receive inappropriate advice, if any, from their primary care practitioners. Some patients report that they feel their physicians are judgmental, do not seem to understand weight issues, and, in many cases, do not offer helpful or appropriate support or resources for losing weight.

**Physician Feedback**

Surveys of physicians are also very informative, providing insights regarding their attitudes toward weight-loss treatment, patients who are overweight, and weight-loss drugs. Some key findings21:

- Three quarters of the physicians who provide weight-loss treatment recommend diet and exercise as first-line therapy.
- Ninety percent of primary care physicians do not always have the time or the desire to actively treat obesity.
- In general, physicians are suspicious of weight-loss medications, largely because of side effects, potential for misuse and abuse, and their perception that patients will rely on drugs to lose weight rather than on establishing healthy lifestyle changes.
- Some physicians are reluctant to treat overweight and obese patients because they feel that these patients are not motivated or committed to losing weight and doing what it takes to keep it off.
- Some physicians are able to differentiate the prescription weight-loss drugs orlistat from sibutramine on the basis of their mechanisms of action and side effects, a reflection of their awareness that these drugs differ not only from each other but also from other weight-loss drugs such as amphetamines and appetite suppressants.

**Initiating Treatment Using Therapeutic Lifestyle Changes**

Initiating lifestyle treatment is fairly straightforward. All patients, regardless of initial body weight, must exercise regularly to achieve and maintain a normal body weight. In addition, patients need to ensure their diets are rich in fruits, vegetables, and whole grain products, dairy products and meats must be low in fat. This is the basis of the new National Cholesterol Education Program guidelines for therapeutic lifestyle changes.22

Even though obesity is now recognized as a serious chronic disease, the medical community as well as patients appear to have significant pessimism about how successful treatment can be. A general perception is that almost no one succeeds in long-term maintenance of weight loss. To identify long-term weight-loss success, an accepted definition is needed. Successful long-term weight-loss maintenance is defined for the purposes of this report as intentionally losing at least 10% of initial body weight and keeping it off for at least 1 year. According to this definition, the picture is much more optimistic, with perhaps more than 20% of overweight and obese persons being able to achieve success. According to the National Weight Control Registry, successful long-term weight-loss maintainers (average weight loss of 30 kg for an average of 5.5 years) share common behavioral strategies, including eating a diet low in fat, frequent self-monitoring of body weight and food intake, and high levels of regular physical activity. Weight-loss maintenance may get easier over time. After these successful maintainers have maintained a weight loss for 2 to 5 years, the chance of longer-term success greatly increases.23

Three basic approaches to motivating weight loss in patients are used to initiate weight-loss treatment. The treatment plan may involve a diet and exercise program, a meal-replacement plan, a weight-loss group, or pharmacologic therapy.24

Of the 3 basic approaches to motivating weight loss, the first is to provide accurate and appropriate
information about losing weight and to advise counting calories. The second is to offer to "work with" the patient who is aware that being overweight is unhealthy. The third approach is to let the patient know the specific health risks he or she faces by being overweight, and then recommend how these risks can be reduced.

Many experts are now recommending a fourth approach, one that acknowledges the involvement of complex behavioral issues and lets the patient know that losing weight is hard work. Underlying all approaches to motivating therapy should be the clear message from the physician that obesity is a medical condition and not a personal or social problem that is the patient's fault.4,6

**Pharmacologic Agents**

Several drugs are available by prescription to facilitate weight loss but only 2 have been approved by the Food and Drug Administration (FDA) for prolonged use: orlistat (Xenical) and sibutramine (Meridia). While many patients are unwilling to consider a drug-based approach because of concerns about side effects, long-term safety, and cost, many others are eager to try a weight-loss drug, with some (Personal communication with James Early, M.D., April 6, 2001) actually switching physicians when they find one who will prescribe the new medications. While cost is a factor to these patients as well, it becomes less of an issue if the drug fulfills, or comes close to fulfilling, the criteria for the ideal weight-loss agent: one that takes weight off, keeps it off, and has no side effects.

Orlistat is a lipase inhibitor that acts by inhibiting the absorption of dietary fats. At the recommended therapeutic dose of 120 mg 3 times daily, it inhibits dietary fat absorption by approximately 30%.22 Because of this, patients who take orlistat and eat more fat than recommended may experience gas with oily discharge, increased frequency of bowel movements, an urgent need to have them, and an inability to control them, particularly after a high-fat meal. Avoiding this may provide an incentive to following a low-fat diet. Because orlistat is also associated with reductions in the absorption of beta-carotene and vitamin E supplements of 30% and 60%, respectively, additional intake of these nutrients, from either dietary sources or supplements, is necessary in patients taking this medication.

The drug is indicated for obesity management, including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. It is also indicated for reducing the risk of weight gain after prior weight loss. In March 2001, a new drug indication was filed with the FDA for glycemic control.22

Orlistat is indicated for patients with an initial BMI of 30 or higher and in patients with a BMI of 27 or higher if hypertension, diabetes, or dyslipidemia is present. It is contraindicated in patients with chronic malabsorption syndrome or cholestasis as well as in patients with known sensitivity to orlistat or any of its components.22

The clinical database for orlistat is extensive, involving about 30 000 patients, many of them diabetic. Pooled data from 5 clinical trials with durations of 1 year revealed that the overall mean weight losses from randomization to the end of 6 months and 1 year of treatment were 12.4 pounds and 13.4 pounds, respectively, in patients treated with orlistat plus a low-calorie weight-loss diet versus 6.2 pounds and 5.8 pounds, respectively, in patients receiving placebo plus diet. Weight loss was observed within 2 weeks of initiation of therapy and continued for 6 to 12 months. After 1 year of treatment, patients in the group receiving orlistat had a 2% reduction in total cholesterol, a 4% reduction in low-density lipoprotein (LDL) cholesterol, a reduction in fasting insulin of 6.7 pmol/L, and a minimal reduction in systolic and diastolic blood pressure. Those receiving placebo had a 5% increase in both total and LDL cholesterol, an increase of 5.2 pmol/L in fasting insulin, and a minimal increase in systolic and diastolic blood pressure.22,25

Treatment effects were then examined for 2 years in 4 of the 5 1-year weight-loss studies. At the end of the first year, the diets were reviewed and modified when necessary, and a weight-maintenance diet was instituted for the second year. Pooled data from the 4 studies showed that orlistat was more effective than placebo in long-term weight control during the second year of treatment as well.22,26
The effect of orlistat on weight regain was evaluated in 3 of the 5 1-year studies. In all 3, patients receiving orlistat had significantly lower rates of regain than did patients receiving placebo (26%, 35%, and 32% versus 52%, 63%, and 53%, respectively).21,25

Sibutramine produces its weight-reducing effects by inhibiting norepinephrine, serotonin, and dopamine reuptake. Like orlistat, it is indicated for the management of obesity, including weight loss and maintenance of weight loss. This drug should be used in conjunction with a reduced-calorie diet. As with orlistat, sibutramine is recommended for obese patients with an initial BMI of 30 or higher and for patients with a BMI of 27 or higher if hypertension, diabetes, or dyslipidemia is present. It is contraindicated in patients receiving monoamine oxidase inhibitors, in those taking other centrally acting appetite suppressants, in those with anorexia nervosa, and in those with hypersensitivity to sibutramine or any of its components. Because sibutramine substantially increases blood pressure in some patients, regular monitoring of blood pressure is required in patients for whom the drug is prescribed. Because sibutramine is also associated with increases in heart rate, it should not be used in patients with a history of coronary artery disease, congestive heart failure, cardiac arrhythmias, or stroke.26

The recommended starting dose of sibutramine is 10 mg once daily. If weight loss is inadequate, the dose may be titrated after 4 weeks to a total of 15 mg once daily. The 5-mg dose should be reserved for patients who cannot tolerate the 10-mg dose.27

Weight loss resulting from sibutramine was examined in 11 double-blind placebo-controlled studies with durations ranging from 12 to 52 weeks. In 2 of the 12-month studies, maximal weight loss was achieved by 6 months and statistically significant weight loss was maintained over 12 months.

In the first of these 2 studies, the mean weight loss among all patients receiving sibutramine 10 mg (n = 154) and sibutramine 15 mg (n = 152) was 9.8 pounds and 14 pounds, respectively, versus 3.5 pounds among all patients receiving placebo (n = 157). Among patients completing the study, the mean weight loss was 13.6 pounds in those receiving the 10-mg dose (n = 80) and 15.2 pounds in those receiving the 15-mg dose (n = 93) compared with 4.8 pounds in 76 patients receiving placebo. For early responders—ie, those losing at least 4 pounds in the first 4 weeks of treatment and who then went on to complete the study—the mean weight loss was 18.2 pounds in the 57 patients receiving the 10-mg dose, 18.8 pounds in the 76 patients receiving the 15-mg dose, and 10.7 pounds in the 24 patients on placebo.26

In the second of these 12-month studies, which compared only the 10-mg dose with placebo, the mean weight loss for all patients was 28.4 pounds for those on active treatment (n = 81) compared with 15.2 pounds for those receiving placebo (n = 78). For those completing the study, the mean weight loss was 29.7 pounds in the treatment group (n = 60) versus 16.7 pounds in the placebo group (n = 48). Among the early responders, the mean weight loss was 33 pounds for those on active treatment (n = 46) and 21.5 pounds for those on placebo (n = 22).26

Analysis of data from 3 studies lasting 6 months revealed that patients who lost at least 4 pounds in the first 4 weeks of therapy were most likely to achieve significant long-term weight loss. Approximately 80% of patients who lost less than 4 pounds during the first 4 weeks of therapy did not go on to achieve a weight loss of 5% of initial body weight by month 6.26

Treatment with sibutramine was associated with beneficial changes in serum lipids and an absence of adverse effects on glycemia. However, it was associated with a mean increase in blood pressure of 1 to 3 mm Hg and with mean increases in pulse rate of 4 to 5 beats per minute relative to placebo. Larger increases in blood pressure and pulse rate were seen in some patients.26

**Patient Support Programs**

Patient support programs have been developed for both orlistat (the XENICare Program) and sibutramine (the Point of Change Weight Management Program) to help patients using these medications learn and incorporate healthy lifestyle changes into their daily lives, to provide ongoing encouragement and support, and to enhance the chances of successful long-term weight loss. Both programs include general and personalized information about weight loss, setting weight-loss goals, nutrition, healthy food choices, calorie and fat content of various foods, menu planning, and tips to motivate patients to continue with their weight-loss programs and achieve their weight-loss goals.22,27

The XENICare program features the availability of a specially trained telephone counselor to provide ongoing support and encouragement, answer ques-
tions that the physician or other health care professional does not have time to answer, and help the patient stay on track.23

The Point of Change program incorporates the LEARN® Program for weight control, a weight-management manual that includes advice on how to remain satisfied with food intake and maintain good health.27

CONCLUDING COMMENTS

Given the epidemic of obesity in America among adults, adolescents, and children, and because excess weight is associated with numerous comorbid conditions, it is essential that all health care professionals, not just those who specialize in obesity management, recognize obesity as a medical problem, implement effective treatments, and help patients lose weight.

At present, several treatment strategies are available for long-term weight loss. These include weight-loss groups, prescribed food plans, meal-replacement plans, a broad range of diets and diet-and-exercise programs, and various pharmacological agents. However, for a weight-loss program to succeed it must recognize and address not only the physiologic and nutritional aspects of diet and exercise, but the emotional and behavioral issues that often underlie obesity. Patients need sound advice and accurate information about proper nutrition, balanced diets, appropriate exercise, realistic goals, and the health advantages of losing weight. Since adhering to a weight-loss program is often a problem, patients also need motivation, encouragement, and ongoing follow-up and support.

Whatever treatment plan is chosen, the physician or dietitian should assure the patient that obesity is a medical condition and not a personal or social problem, that it is amenable to treatment, and that successful weight loss can be achieved.

REFERENCES


22. The third report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and


