Caution Urged on Androgen Therapy for Women

BY CHRISTINE KILGORE
Contributing Writer

The Endocrine Society is sounding a strong word of caution about androgen therapy with a new clinical practice guideline that recommends against diagnosing and treating androgen deficiency in women.

The guideline cites the "lack of a well-defined clinical syndrome" and the "lack of normative data on total or free testosterone levels across the life span" as reasons why a diagnosis should not be made.

On the issue of treatment, the document acknowledges "evidence for short-term efficacy of testosterone in selected populations, such as surgically menopausal women," but says that inadequate indications and insufficient evidence of long-term safety means that the "generalized use of testosterone in women" cannot be recommended (J. Clin. Endocrinol. Metab. 2006;91;3697-710).

"Based on [our literature review], we felt that at this time, we could not, as a committee and a society, recommend either for making the diagnosis or for treatment," said Dr. Margaret E. Wierman, the endocrinologist who chaired the seven-member task force that developed the evidence-based guidelines.

"The quality of the literature was just not up to a standard [needed] to make a global recommendation," said Dr. Wierman, chief of endocrinology at the Veterans Affairs Medical Center in Denver and professor of medicine, physiology, and biophysics at the University of Colorado, Denver. "The sort of hype that testosterone has been given is not yet based on a lot of scientific fact."

Earlier this year, the Endocrine Society issued clinical practice guidelines on androgen deficiency in men, recommending against offering testosterone therapy to all older men with low testosterone levels. (See box.)

The new guideline on androgen deficiency in women has a tone and reach that differs from the less conservative "androgen deficiency" section in the American Association of Clinical Endocrinologists' recently updated menopause guidelines.

Dr. Wierman said she hopes that the new guideline—as well as a document to be released by the Endocrine Society in the next 18-24 months on problems with sex steroid assays for both men and women—will drive development of more sensitive and specific assays. "I think the assay issue will soon be improved," she said.

Physicians must appreciate the fact that the findings on estrogen from the Women's Health Initiative had some impact on the task force, Dr. Wierman said.

"At this point, we felt that the Endocrine Society needs to act as the word of caution so we're not coming back 5 years from now and saying, 'Why weren't we cautious? Why didn't we push our colleagues across academia and research to do the studies to better understand [androgens], so that patients will benefit and won't be harmed?' " she said.

Dr. Steven Petak, president of the American Association of Clinical Endocrinologists, said his organization took a different approach last year in addressing the issue of androgen therapy when updating its menopause guidelines.

"We also were quite cautious, and we agree that long-term safety issues need to be clarified," he said. "But we still went on and stated that there are some criteria for diagnosis, and we gave some recommendations" for the use of androgen.

The Endocrine Society's guidelines "don't do much for patients whose therapies are being considered now," said Dr. Petak of the Texas Institute for Reproduction and Endocrinology. "The Endocrine Society's recommendations for further basic and clinical research in the field are of prime importance and we agree wholeheartedly." ■

Even With Men, Go Slow With Androgen

The Endocrine Society's earlier guideline on androgen deficiency in men advises physicians to offer testosterone therapy on an individual basis to older men with consistently low testosterone levels on more than one occasion and clinically significant symptoms of androgen deficiency.

The guideline advises against the use of androgen therapy in the general population because of a lack of consensus on the case definition and a lack of data on the public health impact of androgen deficiency.

To establish the diagnosis of androgen deficiency in men, a reliable assay should be used to measure the morning total testosterone level. This should be confirmed either by repeating the measurement of morning total testosterone or by measuring the free or bioavailable testosterone level (J. Clin. Endocrinol. Metab. 2006;91:1995-2010).

Testosterone therapy is appropriate in symptomatic men who have classic androgen deficiency syndromes and low testosterone levels, say the guidelines. It should be used to induce and maintain secondary sex characteristics and to improve sexual function, sense of well-being, muscle mass, strength, and bone mineral density.

Testosterone therapy is not appropriate in patients with metastatic prostate cancer, breast cancer, or a palpable prostate nodule or induration. Patients with a prostate-specific antigen (PSA) greater than 3 ng/mL without further urological evaluation are not candidates for testosterone therapy. Other contraindications include erythrocytosis and hyperviscosity. With a lack of randomized controlled trial data, there was no recommendation on treating men with prostate cancer who have been disease free for 2 years or more.

The task force recommended a standardized monitoring plan with evaluation and measures of testosterone levels at 3 months after initiating treatment and annual assessments.

Hematocrit should be measured at baseline, at 3 months, and annually. If hematocrit exceeds 54%, therapy should be stopped until hematocrit decreases to a safe level. Therapy can be restarted at a lower dosage, but evaluations for hypoxia and sleep apnea should be conducted.

Urological consultation is recommended if there is a verified serum or plasma PSA concentration of more than 4.0 ng/mL or an increase in serum or PSA concentration of more than 1.4 ng/mL in a 12-month period.

—Mary Ellen Schneider

FDA Targets Firms Marketing Sham Diabetes Products on the Internet

BY ELIZABETH MECHCATIE
Senior Writer

The sale of products that are misrepresented as cures or treatments for diabetes and the Internet sites that advertise these products are the target of a campaign launched by U.S., Mexican, and Canadian government agencies.

The Food and Drug Administration and the Federal Trade Commission (FTC) announced in a statement that the FDA had issued 24 warning letters to companies marketing dietary supplements with claims that the products treated, cured, prevented, or mitigated diabetes. To date, about 180 letters and other advisories have been sent to online outlets in the three countries as a result of the campaign.

The FTC also announced a new campaign aimed at educating consumers about how to avoid falling for sham diabetes cures. Included is an example of a Web site promoting a phony product called Glucobate.

"The Internet can be a great source of information, but it also is a billboard for ads that promise miracle cures for diabetes and other serious diseases," Lynda Parnes, director of the FTC's Bureau of Consumer Protection, said in the statement.

"We will not tolerate practices that raise false hopes and bilk consumers of precious health care dollars," Margaret O'K. Glavin, the FDA's associate commissioner for regulatory affairs, said in the statement.

An example of one warning letter, sent by the FDA to a Reno, Nev.–based company about its product called "Enhansulin," notes that the product is advertised as containing extract from "Caucasian blueberry leaves." The letter says that marketing this product with the therapeutic claims that appear on its Web site establishes it as a drug and, therefore, violates the Federal Food, Drug, and Cosmetic Act. Among the claims on the Web site, according to the letter, is the statement that Caucasian blueberry leaves have been "effectively used to manage the effects of diabetes" for centuries.

The list of the 24 companies that have been sent warning letters, with links to the letters, is on the FDA's Web site at http://www.cfsan.fda.gov/~dms/dialist.html. The phony ad created by the FTC as part of its consumer education campaign is available at: http://wemarket4u.net/glucobate/ index.html. ■

Warning on Counterfeit Glucose Tests Stresses Misinformation

Some blood glucose test strips being sold in the United States are counterfeit and potentially could provide patients with incorrect information on blood glucose values, according to an alert issued by the Food and Drug Administration.

Certain lots of two types of test strips used with different models of OneTouch–brand blood glucose monitors have been found to be counterfeit and are being voluntarily recalled by the manufacturer, LifeScan Inc. The counterfeit test strips are:

- OneTouch Basic/Profile (lot #272894A, 2619932, or 2606340) test strips. (The outer cartons of these strips have English, Greek and Portuguese text; and only 50-count packages are affected.)
- OneTouch Ultra (lot #2691191) test strips. (The outer cartons of these strips have English and French text; only 50-count packages are affected).

The counterfeit strips were distributed to stores and pharmacies across the country, but primarily were sold in Ohio, New York, Florida, Maryland, and Missouri by Medical Plastic Devices Inc., Pointe Claire, Que.; and Champion Sales Inc., Brooklyn, N.Y, according to the alert.

The FDA is advising consumers to stop using these counterfeit strips if they have purchased them, replace the strips immediately, and call their physicians. The company is advising customers to contact their original source of the strips for restitution.

The FDA, which is investigating this case, has not received any reports of injuries related to the counterfeit strips, but encourages physicians and others to report any adverse reactions associated with the use of this product and/or quality problems to the FDA's MedWatch program at 800-332-1088, or www.fda.gov/medwatch.

—Elizabeth Mechcatie

LifeScan can be reached at 866-621-4855, if consumers have any questions. More information is also available at www.GenuineOneTouch.com.