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HIGHLIGHTS:

Although they are considered “male” hormones, certain levels of androgens normally circulate in the bloodstreams of women as well as men. But when women’s bodies produce excessive amounts of androgens, symptoms can range from annoying to serious. Researchers at Cedars-Sinai Medical Center and the University of Alabama at Birmingham, completing what may be the largest long-term study of women with androgen excess, find that some of the most problematic symptoms can be reduced when treated with a combination of therapies. Their findings, based on 15 years of experience, are published in the February issue of the *Journal of Clinical Endocrinology and Metabolism*.

LARGE-SCALE ANALYSIS OF WOMEN WITH ANDROGEN EXCESS: THOROUGH TREATMENT CAN REDUCE SYMPTOMS

LOS ANGELES (Feb. 4, 2004) – Although women normally have androgens – so-called “male” hormones – circulating in their bloodstreams, excessive levels can cause a variety of symptoms including acne, weight gain, excessive hair growth (hirsutism), menstrual dysfunction, and infertility.

Hirsutism – the growth of coarse hair in patterns similar to those of men – has long been considered the key marker for androgen excess. Physicians have had difficulty providing a firm diagnosis and identifying underlying causes, however, because a number of disorders can cause hirsutism, not all women with hirsutism have evidence of androgen excess, and not all patients who have androgen excess disorders suffer from hirsutism. Determining the most effective treatment has been challenging, too. While most women have been treated with single-agent hormone therapy, a combination approach has been suggested as a better alternative, but comparison studies have been conducted in only small samples of patients.

Now a long-term study – perhaps the largest of its kind to date – identifies the most common causes of androgen excess in women and compares therapeutic approaches, showing that combination hormonal therapy can improve most symptoms. Researchers at Cedars-Sinai Medical Center and the University of Alabama at Birmingham report their findings in the February issue of the *Journal of Clinical Endocrinology and Metabolism* in an “Extensive Personal Experience” article.

(more)

The study offers optimism for women suffering from most symptoms of androgen excess disorders, but it also points out that specialists must do more to inform and educate patients about the potential benefits of long-term treatment, according to Ricardo Azziz, MD, MPH, MBA, who directs Cedars-Sinai's Center for Androgen Related Disorders (CARD), the only center of its kind in Southern California.

"More than 80 percent of androgen excess patients who were compliant with their therapy experienced an improvement in hirsutism, menstrual dysfunction, and acne, but many patients dropped out of treatment or were not compliant. Our data suggest that we must identify strategies for improving the level of education and support for women suffering from these difficult disorders," said Dr. Azziz, Chair of Cedars-Sinai's Department of Obstetrics and Gynecology and Executive Director of the Androgen Excess Society, an international research organization.

Before joining Cedars-Sinai, where he holds The Helping Hand of Los Angeles Chair in Obstetrics and Gynecology, Dr. Azziz served as Professor in the Department of Obstetrics and Gynecology and in the Department of Medicine at the University of Alabama at Birmingham. He now is Professor and Vice-Chair of the Department of Obstetrics and Gynecology and Professor in the Department of Medicine at The David Geffen School of Medicine at UCLA.

The study period extended from 1987 to 2002, during which 1,281 consecutive patients with possible symptoms of androgen excess were evaluated at the University of Alabama. Of those, 873 cases qualified for inclusion in the study.

Two-thirds of patients seeking help were 30 years old or younger, with 20 percent below age 20 at the time of their first visit. However, because most androgen excess disorders begin around the onset of puberty, most women appear to suffer many years without medical intervention. In fact, the researchers estimate that "up to 80 percent of patients are not recognized, evaluated or treated in a timely fashion."

Although androgen excess is recognized as the most common endocrine disorder among women in their reproductive years, its causes are not always easy to determine. In this large sample, only 59 patients (6.75 percent of the total) had specific identifiable underlying disorders. These included a very small number of cancers, classic and non-classic adrenal hyperplasias, and hyperandrogenic insulin-resistant acanthosis nigricans (HAIRAN) syndrome.

In contrast, 93.24 percent of patients were diagnosed based on symptoms and the exclusion of other disorders. About 82 percent were found to have an endocrine disorder called polycystic ovary syndrome (PCOS), 4.47 percent had idiopathic or unexplained hirsutism, and 6.75 percent had elevated androgen levels and hirsutism but normal ovulation. Women with PCOS often have numerous small cysts on the periphery of the ovaries. Many are found to have insulin resistance, a condition that allows excessive levels of insulin to circulate in the blood and increases the risk for Type 2 diabetes, hypertension and heart disease.

In the study, more than 75 percent of patients seeking medical attention suffered from hirsutism, 14 percent of patients had acne, and nearly 30 percent complained of infertility. About 88 percent of patients had infrequent ovulation, and 86 percent of this group exhibited obvious menstrual dysfunction. Also, patients with androgen excess disorder were about twice as likely as the general population to be obese.

When treated with combination therapies to suppress androgen production and/or block the hormones' actions, improvement was seen in 86 percent of women with hirsutism, acne improved in 81 percent of cases, and menstrual dysfunction improved in 80 percent. Hair loss – a less common symptom of androgen excess – improved in only 33 percent of patients.

While more than 60 percent of treated patients had such side effects as irregular vaginal bleeding, nausea and headaches, these symptoms were not considered serious, but they may have contributed to a high number of patients discontinuing treatment. Of 501 patients seeking hormonal suppression therapy, about 50 percent failed to follow up or were noncompliant with treatment.

“The overwhelming majority of women with hirsutism have an underlying androgen disorder, which they typically discover only after they have sought electrolysis or other methods for dealing with this embarrassing symptom,” said Dr. Azziz. “But about 25 percent of our patients with excessive levels of androgen are non-hirsute, making it even more difficult for them to find the help they need. Many women with acne, many who have been unable to become pregnant, and many who have struggled with their weight may also be found to suffer from excess androgen disorder. This study supports the recommendation that even in the absence of hirsutism, more women should receive comprehensive endocrine evaluations, which would make many aware of treatments available to improve their lives.”

The study was supported in part by National Institutes of Health Grants RO1-HD29364 and K24-D01346 to Dr. Azziz.

Cedars-Sinai is one of the largest nonprofit academic medical centers in the Western United States. For the fifth straight two-year period, it has been named Southern California's gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. It ranks among the top 10 non-university hospitals in the nation for its research activities.

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