EDITORIAL

Do You Trust Your Testosterone Level?

Serum determination of circulating levels of testosterone is a relatively common test in urologic practice. Other disciplines also rely on the accurate measurement of testosterone such as endocrinologists and gynecologists. Testosterone determinations have utility in the evaluation of a variety of conditions in both men and women such as hypogonadism that may cause male erectile dysfunction and infertility, precocious puberty, irregular menses, hirsutism and determining the effectiveness of prostate cancer treatments that intentionally lower testosterone levels. Low levels of testosterone have long been recognized as causing the classic changes of male aging including loss of vitality, decreased libido, increased abdominal body fat and reduced muscle mass and strength. Additional adverse physiologic effects of testosterone deficiency in adult males such as cardiovascular disease and myocardial infarction, dementia, metabolic syndrome with glucose intolerance, and osteoporosis have become increasingly recognized. These adverse physiologic changes have re-focused efforts on testosterone replacement therapy strategies in older men. A growing list of pharmaceutical agents with differing modes of administration designed to increase circulating testosterone levels have become available in the last few years with all requiring periodic monitoring of testosterone levels.

LHRH analogues and antagonists used in advanced prostate cancer can demonstrate significant variability in the degree of suppression of testosterone to so called "castrate" levels, traditionally defined as a testosterone of < 50 ng/dL. Levels are also important in the application of intermittent hormonal therapy. Newer prostate cancer drugs such as abiraterone and others in development will further challenge current assay techniques as they are capable of reducing circulating testosterone levels far below the traditional "castrate" level of testosterone. Whether for diagnostic purposes or monitoring therapeutic responses to testosterone replacement therapy, reliance on accurate laboratory determinations of serum testosterone is becoming increasingly important.

With the growth in research and clinical applications that rely on accurate serum levels of testosterone, significant problems exist with the measurement of this key hormone. The underlying problem is the lack of a single, agreed-upon standard method for measuring testosterone in serum or plasma. There is significant concern that many testosterone assays do not provide accurate results across the range of testosterone concentrations important to patient care, particularly when measured at very low concentrations. The CDC began a project in 2007 to design a workable standard for testosterone assays. This collaboration with academic and industry researchers will develop these reference materials and calibration procedures. The issue of testosterone assay accuracy was highlighted in an interdisciplinary consensus statement published last year.[1] The consensus statement was led by the Endocrine Society with the endorsement of many other organizations including the American Urological Association. In addition to medical societies and the CDC, the FDA along with major commercial clinical labs are involved in these discussions. Assay methods, patient preparation, specimen handling and revised normal population based values must all be included in the standardization.

Until the full range of standardized testosterone values from children to adult males and females are available from commercial laboratories, the following procedures should be used. Due to the circadian rhythm, collect an early morning sample and have the sample promptly processed. Use the same laboratory and assay method for intra-patient consistency. Repeat any sample that is a borderline value. With these initiatives moving ahead, assay standardization should take place in the next few years that will reassure both healthcare providers and patients that the testosterone level reported can be trusted to guide clinical care.

Reference

1. Rosner W, Vesper HJ. Toward excellence in testosterone testing: a consensus statement. *Clin Endocrinol Metab* 2010;95(10):4542-4548.

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