Abstract citation ID: bvad114.1622

Reproductive Endocrinology

FRI431

Erythrocytosis Associated With Oral Testosterone Replacement

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Disclosure: A.A. Engel: None. **J.L. Sarvaideo:** None.

Background: A growing prevalence in male hypogonadism has led to increased interest in the most common adverse event, erythrocytosis. Defined by hematocrit (HCT) > 49-51%, the incidence varies depending on the testosterone formulation.[3] The formulations with the lowest risk of erythrocytosis are intranasal testosterone (0-2%) and oral testosterone (0.03%).[3] A phase 3 clinical trial of testosterone undecanoate (Jatenzo) reported 4.8% patients experienced an increase in hematocrit, although not severe enough to warrant therapy discontinuation.[2] We present a case of erythrocytosis with oral testosterone undecanoate that prompted a change in therapy. **Clinical Case:** Our patient is a 55-year-old male with secondary hypogonadism potentially related to obesity (BMI 37 kg/m^2). AM total testosterone (TT) 151 (348-1197 ng/dL), free testosterone 4.6 pg/mL (6.8-21.5 pg/mL) and LH 3.8 mIU/mL. Labs confirmed. Secondary work-up negative. HCT 43.6% prior to any therapy. Patient treated with injectable testosterone. Despite decreasing to testosterone cypionate 80 mg weekly his HCT increased to 52.7% with a TT of 544 ng/dL. He was switched to oral testosterone undecanoate 237 mg twice daily given presumably lower risk of erythrocytosis. However, HCT increased to 55.1% and TT to 1542 ng/dL. Patient donated blood and oral testosterone dose decreased to 158 mg twice daily with starting HCT 48.9%, but this increased to 53.7%. TT 522 ng/dL. Therapy stopped with improvement of HCT to 45.8%-48.9%, TT 192 ng/dL, and SHBG 20 g/dL. Erythropoietin remained normal. Patient does not smoke cigarettes nor has OSA. **Conclusion:** We present a case of oral testosterone undecanoate complicated by persistent erythrocytosis despite dose reduction. Testing for contributing etiology was unrevealing. Oral testosterone replacement is considered the formulation least likely to cause erythrocytosis. Certain patient characteristics like OSA, advanced age, obesity, type II diabetes mellitus and an elevated HCT > 50% can predict the likelihood of erythrocytosis although its specific etiology is unclear.[3] Proposed mechanisms include elevation in dihydrotestosterone, erythropoietin stimulation, suppression of hepcidin and relation to androgen receptor CAG repeat length.[1] Providers should be aware of the possibility of erythrocytosis on oral testosterone. Further research is needed to determine predictive characteristics for erythrocytosis and etiology.

Reference: 1. Aghazadeh, M, et al. Elevated dihydrotestosterone is associated with testosterone induced erythrocytosis. *J Urol.* 2015; 194(1): 160-165. **2.** Swerdloff, S, et al. A new oral testosterone undecanoate formulation restores testosterone to normal concentrations in hypogonadal men. *J Clin Endocrinol Metab*. 2020; 105)8): 1-17. **3.** White, J, et al. Testosterone therapy and secondary erythrocytosis. *IJIR: Your Sexual Medicine Journal*. 2022; 34: 693-697.

Presentation: Friday, June 16, 2023

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