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differences of KS age between Italian geographical regions highlight the need for increased awareness leading to timely detection.

DOI: 10.1530/endoabs.63.P319

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Gonadal Function in Human Immunodeficiency Virus (HIV)-Infected Men: comparison between Isotopic Dilution-Liquid Chromatography-Tandem Mass Spectrometry (ID-LC-MS/MS) and Chemiluminescent Immunoassay (CI)

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Background

HIV-infection is associated to premature decline of serum T. However, prevalence and biochemical characterization of hypogonadism in HIV-infected men are still to be well defined.

Aim

To evaluate the gonadal status in HIV-infected men by assessing circulating total T (TT) with either ID-LC-MS/MS or CI.

Methods

Prospective, cross-sectional, observational study on HIV-infected men with ongoing Highly Active Antiretroviral Therapy (HAART). Serum TT, gonadotropins and sex hormone-binding globulin (SHBG) were measured by CI (Architect, Abbott, USA). TT was also assessed by a validated in house ID-LC-MS/MS. Free T (FT) was calculated by Vermeulen equation. Hypogonadism was defined as serum TT levels below 320 ng/dl and/or free T levels below 64 pg/ml. **Statistical analysis:** Parameters were not normally distributed and Mann-Whitney U test, was used to compare continuous variables. Categorical variables were compared using Chi-Square test, while correlations were performed using linear regression models.

Results

315 consecutive HIV-infected men were enrolled (mean age 45.56 ± 5.61 years; average duration of HIV-infection 16.57 ± 10.45 years). Serum TT levels assessed by LC-MS/MS (mean 652.1 ± 229.1 ng/dl) were significantly lower compared to CI (mean 740.2 ± 274.7 ng/dl) ($P < 0.0001$). As a consequence, prevalence of T deficiency was significantly higher comparing LC-MS/MS to CI (5.4% vs 3.2%, $P < 0.0001$). 56 patients (17.8%) showed SHBG above the normal range (> 71.4 nmol/l). Considering calculated FT, the prevalence of hypogonadism was 9.8% using LC-MS/MS and 7.0% using CI, with a significant difference between methodologies ($P < 0.0001$). TT assessed with LC-MS/MS was directly related to TT assessed with CI (Beta = 0.956, $R^2 = 0.913$, $P < 0.0001$), as well as FT (Beta = 0.934, $R^2 = 0.873$, $P < 0.0001$). TT combined with luteinizing hormone (LH) levels was used to classify hypogonadism. By including compensated form of hypogonadism, the prevalence raised to 15.6% for TT and to 17% for FT.

Conclusions

To the best of our knowledge, this is the first properly-designed prospective study aiming to investigate the gonadal status of HIV-infected men with both LC-MS/MS and CI, together with gonadotropins. Notwithstanding the strong correlation found between the two methodologies, the prevalence of hypogonadism results underestimated when CI is used compared to ID-LC-MS/MS in HIV-infected patients. In clinical practice, SHBG for calculated FT is essential for the detection of T deficiency, revealing the real prevalence of hypogonadism in this clinical setting.

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P321

Automated free testosterone assay: validation and usual values

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Introduction

Testosterone circulates under different forms in blood, mainly bound to proteins i.e. Sex Hormone Binding Globulin (SHBG) and albumin. Free testosterone (FT), the biologically active form, represents 2% of total testosterone (TT). FT measurement is mainly indicated when TT level is discordant with clinical picture but remains technically challenging. Indeed, as for all free hormones, gold standard method relies on equilibrium dialysis, unusable in routine. Direct immunoassays by competition have thus been designed, traditionally based on sensible radioactive detection signal (RIA). FT can also be calculated from TT, SHBG and albumin levels. Our work aimed to compare a new automated immunoassay to preexisting dosages and to propose adapted usual values.

Materials and methods

Analytical performances of this new FT assay were evaluated. FT was therefore determined in 164 patients (68 women, 96 men) using the new immunoassay (IS-5300, IDS-iSYS Free Testosterone), a RIA immunoassay (KIP119000, DAsource), and a calculation based on TT (RIA TESTO-CT2, Cisbio), SHBG, and albumin (Cobas ROCHE) concentrations. Usual values for the new dosage were established.

Results

Analytical performances of the new assay claimed by the manufacturer were confirmed and comparable with those of the RIA assay except for a higher detection limit. Correlation between immunoassays was satisfactory in men ($R^2 = 0.77$) but weaker in women ($R^2 = 0.45$), results with the new automated dosage being globally 30% lower. Correlation between both immunoassays and calculated FT was also satisfactory in men (respectively $R^2 = 0.68$ for automated and 0.76 for RIA immunoassays) and poor in women (respectively $R^2 = 0.15$ and 0.13). Calculated FT was much higher than measured FT, as the corresponding reference values proposed by the manufacturers. This discrepancy was confirmed by the analysis of external quality controls results whatever the direct immunoassay. We proposed preliminary usual values (minimal and maximum values observed in the subgroup of patients with normal testosterone and SHBG levels): 18.9–51.7 pmol/l in men < 50 years old ($n = 23$); 7.4–39.5 pmol/l in men > 50 years old ($n = 33$); < 6.2 pmol/l in women < 50 years old ($n = 34$) and < 4.3 pmol/l in women > 50 years old ($n = 23$).

Conclusion

IDS-iSYS FT assay is one of the first automated assays allowing FT dosage. Its analytical performances are suitable and provide valuable results in comparison to both RIA immunoassay and calculated FT, at least in men. Clinicians should pay attention to FT usual values indicated by the laboratories, given the large differences observed, particularly between direct immunoassays and calculated FT.

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P322

Assessment of biochemical hyperandrogenism in PCOs by liquid chromatography tandem mass spectrometry using a multiteroid kit: focus on testosterone and androstenedione

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Objective

The identification of hyperandrogenism represents the cornerstone for the assessment of polycystic ovary syndrome (PCOs). However, its definition has always been troubling, mostly because of the poor accuracy shown by routine

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