

## PP 012 - 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)

M. C. Decaroli<sup>1</sup>, S. De Vincentis<sup>1</sup>, F. Fanelli<sup>2</sup>, M. Mezzullo<sup>2</sup>, C. Diazzi<sup>1</sup>, F. Morini<sup>1</sup>, D. Bertani<sup>1</sup>, D. Santi<sup>1</sup>, E. Baraldi<sup>3</sup>, S. Tagliavini<sup>3</sup>, L. Roli<sup>3</sup>, T. Trenti<sup>3</sup>, U. Pagotto<sup>2</sup>, G. Guaraldi<sup>4</sup>, V. Rochira<sup>1</sup>

<sup>1</sup>Unità di Endocrinologia, Dipartimento di Scienze Biomediche, Biometaboliche e Neuroscienze, Università di Modena e Reggio Emilia; <sup>2</sup>Unità di Endocrinologia, Dipartimento di Specialità Mediche, Azienda Ospedaliero-Universitaria di Modena Modena, <sup>3</sup>Unità di Endocrinologia e Centro di Ricerca Biomedica Applicata (CRBA), Dipartimento di Scienze Mediche e Chirurgiche, Università di Bologna – Ospedale Sant'Orsola-Malpighi, Bologna Bologna, <sup>4</sup>Dipartimento di Medicina di Laboratorio e Anatomia Patologica, Azienda USL di Modena Modena, <sup>4</sup>Clinica Metabolica Multidisciplinare, Unità di Malattie Infettive, Università di Modena e Reggio Emilia Modena

**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<sup>2</sup>=0.913, p<0.0001), as well as FT (Beta=0.934, R<sup>2</sup>=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.