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Fund "Nauka" Project № 11011 Resume – Competition-Based Session 2011:

"Determination of total and free testosterone in serum and saliva in patients having obstructive sleep apnea"

Project leader: Prof. Diana Petkova Gospodinova-Valkova, MD, PhD **Project leader:** Prof. Yana Dimitrova Bocheva, PhD

Obstructive sleep apnea (OSA) is a disease with a high frequency in the modern population, affecting at least 4% of men and about 2% of women. OSA is associated with various disorders such as cardiovascular disease, insulin resistance, diabetes mellitus, sexual disorders and erectile dysfunction. In some patients, low testosterone plasma levels have been found, which is associated with the occurrence of erectile dysfunction. The true incidence of low plasma total testosterone levels and the relationship to the sexual health of these patients are poorly studied and still undefined. Data from single studies indicate that CPAP therapy in OSA results in an increase in plasma total testosterone levels, but it remains unclear whether this leads to clinical improvement in patients with regard to libido and sexual function.

A major problem and scientific challenge in the clinical laboratory in the determination of free testosterone and total testosterone in women and children is the validation of a methodology that is sensitive in the low concentration range. Compared to the liquid chromatography/ tandem mass spectrometry principle analysis, the routinely used immunoassay gives serious deviations, especially in the low regions. Over the past year, a number of automated immunoassay reagent manufacturers have announced the development of a testosterone assay sensitive in the low concentration range. Validation of its sensitivity for the reliable determination of low testosterone concentrations in women, children and men with hypogonadism, as well as its adaptation for the determination of free testosterone levels in men in plasma and saliva would bring a substantial scientific-applied contribution to laboratory endocrinology.

In accordance with the set goals of the project, the following **results** were achieved:

- 1. Plasma levels of total and free testosterone and salivary levels of free testosterone were determined in healthy male and female controls by means of a routine immunoassay;
- 2. Reference limits for free testosterone in men in saliva were developed for the first time in our country;
- 3. Total and free testosterone levels and salivary free testosterone levels in newly diagnosed patients with obstructive sleep apnea were determined;
- 4. Partial validation of the II generation immunoassay for the determination of total testosterone was performed;

- 5. Directly determined and standard formula free testosterone levels in serum were compared;
- 6. A statistical evaluation of the correlation between serum free and salivary testosterone was performed.

In the course of the work on the project, two of the participants in the research project defended their doctoral theses and were habilitated.

Publicity of the results

Scientific publications and participations (preliminary publications):

- 1. Petkova D, Yotov Y, Paskalev D, Bocheva Y, Andonova S, Usheva N. N-terminal B-type natriuretic (NT-ProBNP) in patients with obstructive sleep apnea syndrome. Scripta Scientifica Medica, 2011, vol 43 (1), 7-10;
- 2. Bocheva Y, Petkova D, Yotov Y, Banova B, Usheva N. Determination of NT-ProBNP in patients with obstructive sleep apnea syndrome. First European Joint Congress of EFCC and UEMS; 13-16 October 2010, Lisbon, Portugal. Book of abstracts, 165;
- 3. Bocheva Y, Petkova D, Shishkov, R. Steroid hormones and sleep disorders. Thoracic Medicine, Volume III 2011 (3), 18-24;
- 4. D. Petkova, Y. Bocheva, Serum levels of total testosterone and sex hormone-binding protein in patients with obstructive sleep apnea syndrome; Fourth Congress of the Bulgarian Society of Pulmonary Diseases, Sofia, 14-16.06.2012.