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SEXUAL FUNCTION OF HYPOGONADAL MEN WITH ERECTILE DYSFUNCTION (ED) IN THE TRIUS COHORT: MULTIPLE DOMAINS SIGNIFICANTLY CORRELATED WITH SERUM T LEVELS

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Background: The Brief Male Sexual Function Inventory (BMSFI) provides a self-reported measure of the various domains of male sexual function. The purpose of this report was to assess if baseline serum testosterone (T) levels in hypogonadal men with erectile dysfunction (ED) correlated with BMSFI scores and to assess which domains of the BMSFI had the strongest bivariate correlation with serum T levels.

Methods: Patients were drawn from 849 men enrolled in TRiUS, a prospective observational cohort registry of hypogonadal men on testosterone replacement therapy with Testim. ED was defined as current usage of a PDE5 inhibitor. Baseline mean T levels from hypogonadal men with ED were correlated (Pearson r) with total BMSFI scores and each of the 5 BMSFI domains; ie, libido, erections, ejaculatory function, level of bother having ED, and overall sexual satisfaction.

Results: Baseline BMSFI scores from 106 hypogonadal men with ED with a mean age of 57 years (R, 32-84) were available for analysis. Baseline mean testosterone value was 214 ng/dL (R, 1.98 — 299 ng/dL). Mean ± SD BMSFI scores were libido (2.48 ± 0.94), erectile function (2.29 ± 1.04), ejaculatory function (3.09 ± 1.34), level of bother having ED (2.19 ± 1.09), overall sexual satisfaction (2.06 ± 1.05), and total (2.47 ± 0.92). Total, erectile function, ejaculatory function, and problem assessment scores were all significantly lower than previously published normative data for men in the fifth decade. Total BMSFI scores correlated with serum total T levels ($r = 0.23$, $p = 0.02$). Serum T levels also correlated with 4 of the 5 BMSFI domains: libido ($r = 0.21$, $p = 0.04$), ejaculatory function ($r = 0.23$, $p = 0.02$), level of bother having ED ($r = 0.25$, $p = 0.01$) and overall sexual satisfaction ($r = 0.20$, $p = 0.05$). Serum T levels did not correlate with erectile function ($r = 0.07$, $p = 0.52$).

Conclusion: These results provide further evidence that hypogonadal men have significantly more sexual problems than eugonadal men of the same age. In hypogonadal men with ED, serum T levels appear to correlate significantly with overall sexual function based on the total BMSFI and the domains scores for libido, ejaculatory function, level of bother having ED, and overall sexual satisfaction but not erectile dysfunction.

doi:10.1016/j.jomh.2009.08.083

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CHANGES IN BODY COMPOSITION, LIPID PROFILE, SERUM FIBRINOGEN, SERUM FASTING GLUCOSE AND RED BLOOD CELL COUNT IN MEN ON LOG-TERM ANDROGEN DEPRIVATION THERAPY

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Background: Prostate cancer (PCa) is one of the most common malignancies in men. Androgen deprivation therapy (ADT) is considered the standard therapy for advanced PCa, but its use may be associated with several adverse effects. The aim of this study was to determine the changes of body mass index (BMI), waist-hip ratio (WHR), lipid profile, fibinogen, fasting glucose and red blood cell count after 12 months of ADT.

Methods: Seventy-six pacients with locally advanced PCa (mean age 75,4 yrs) were treated with ADT for at least 12 months. BMI, WHR, lipid profile, fibinogen, fasting glucose and red blood cell count were assesed before the initiation of ADT and then after 12 months. These measurements were also made to the control group of sixty-five patients (mean age 74,7 yrs)

Results: BMI, WHR, LDL, TAG, VLDL increased significantly ($p < 0,001$), overall cholesterol, serum fibrinogen, fasting serum glucose increased significantly ($p = 0,01$, $p = 0,03$, $p = 0,05$) respectively. HDL increased insignificantly ($p = 0,245$), red blood cell count decreased significantly ($p < 0,001$), in the study group.

Conclusions: ADT leads into unfavourable changes in body composition, unfavourable lipoprotein profile, increase in serum fibrinogen and fasting glucose level. These data suggest that patients on long term ADT are at higher risk of cardiovascular morbidity, of developing insuline resistance and anemia. Physicians should be aware of these adverse effects which may increase mortality and consider preventive (lifestyle) actions to reduce this risk.

doi:10.1016/j.jomh.2009.08.084

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THE EFFICACY AND SAFETY OF ONCE-DAILY DOSED UDENAFIL [ZYDENA®] IN PATIENTS WITH ERECTILE DYSFUNCTION

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Background: On-demand dosing of phosphodiesterase type5 (PDE5) inhibitors is a current therapeutic regimen for men with erectile dysfunction (ED). However, continuous daily administration of PDE5 inhibitors has been recently proposed for better management of ED. This study was performed to evaluate the safety and efficacy of udenafil [Zydena®], a selective PDE5 inhibitor, dosed once daily for the treatment of ED.

Methods: In this multicenter, randomized, double-blind, placebo-controlled, parallel-group study, eligible 239 patients were randomly assigned to take placebo, 25 mg of udenafil, 50 mg of udenafil or 75 mg of udenafil once daily for 12 weeks following a 4-week, treatment-free run-in period. Primary efficacy measure was the change from baseline in the International Index of Erectile Function (IIEF) erectile function (EF) domain score. Secondary efficacy measures included the change from baseline for the Sexual Encounter Profile (SEP) diary question 2 and question 3, the rate of achieving normal erectile function (IIEF-EF domain score 26-30) and the response to Global Assessment Question (GAQ).

Results: Compared to placebo, patients receiving 50 mg udenafil and 75 mg udenafil showed significant improvement in the IIEF EF domain score, and those changes were larger in higher-dose group: placebo, 3.14; 25 mg udenafil, 4.67; 50 mg udenafil, 6.59; 75 mg udenafil, 8.34, respectively. Similar significant improvements were found in SEP Q2 and Q3: placebo, 11.95% and 23.46%; 50 mg udenafil, 27.90% and 51.41%; 75 mg udenafil, 39.11% and 73.50%, respectively. The proportions of achieving normal erectile function were 30.5%, 40.0%, and 44.1% in 25 mg udenafil, 50 mg udenafil, and 75 mg udenafil group, respectively, which were significantly higher than that of placebo group (13.6%). Likewise, the rates of patients responding positively to the GAQ were significantly higher in the udenafil treated groups than placebo. Treatment with udenafil was well tolerated with a low incidence of common treatment-emergent adverse events. The most commonly reported adverse events were headache and flushing (placebo, 0% and 1.7%; udenafil, 1.7% and 5.6%, respectively) which were transient and mild in nature.

Conclusion: Once-a-day udenafil significantly efficacious for the treatment of ED and well tolerated.

doi:10.1016/j.jomh.2009.08.085

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CORRELATION BETWEEN BASELINE TESTOSTERONE (T) LEVELS AND PSA IN THE TRIUS COHORT: LOW PSA LEVELS ARE SIGNIFICANTLY CORRELATED WITH LOW T VALUES

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Background: The prostate saturation theory suggests that lower testosterone (T) values are more likely to correlate with changes in PSA values and prostate growth than higher levels of T. We studied testosterone and PSA values in a cohort of hypogonadal men with varying levels of serum T enrolled in the Testim Registry in the United States (TRiUS) to assess if lower PSA values were associated with lower serum T levels.

Methods: The 849 patients enrolled in TRiUS, a prospective observational cohort registry of hypogonadal men on replacement therapy with Testim were grouped based on baseline T levels: < 250 ng/dL and ≥250 ng/dL. Men with serum T < 250 ng/dL were further stratified as follows: serum T values of < 150 ng/dL (Group I), 150—200 ng/dL (Group II), and 201—249 ng/dL (Group III). Spearman correlation coefficients controlling for age with PSA values were assessed. Analysis of covariance was used to assess differences in mean PSA values among the different groups, controlling for age.

Results: Baseline serum PSA and T levels were available for 449 men. Of these, 198 men with a mean age of 55 years (R, 28—83) had total serum T values < 250ng/dL. Mean total and free T values were 187 ng/dL and 29.6 pg/dL, respectively. The mean PSA value was 1.04 ng/mL. Mean PSA values correlated with serum total T values ($r = 0.21$, $p = 0.0032$). Mean PSA values also significantly correlated with serum free T and SHBG levels ($r = 0.20$, $p = 0.04$ and $r = 0.59$, $p = 0.002$, respectively). Mean PSA values differed significantly ($p = 0.02$) among Groups I (0.86, $n = 40$), II (0.88, $n = 62$), and III (1.22, $n = 96$). Age was a highly significant covariate ($p < 0.0001$), and mean PSA values remained significantly different ($p = 0.02$) after controlling for age. Among the 251 (56%) men with total T values ≥250 ng/dL, the mean serum T was 362 ng/dl. The mean serum PSA was 1.2 ng/mL. In these men, there were no significant correlations of PSA, controlling for age, with serum total T, free T, and SHBG levels, ($r = 0.09$, $p = 0.15$, $n = 251$), ($r = 0.01$, $p = 0.92$, $n = 184$), and ($r = -0.08$, $p = 0.51$, $n = 67$), respectively).

Conclusion: While PSA values do not appear to significantly correlate with serum total and free testosterone and SHBG when serum T is at eugonadal level, they significantly correlate at lower T levels. The TriUS baseline data support the prostate saturation theory and suggest that men with low serum T may present with lower PSA values. These correlations will be reevaluated at 6 and 12 months.

doi:10.1016/j.jomh.2009.08.086