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In Men on Testosterone Therapy, Baseline Testosterone Level of <264 ng/dL is Associated with Greater Improvement in Body Composition, While Level of \geq 264 ng/dL Favors Improvement in Metabolic Profile

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Context: Male hypogonadism adversely affects body composition, bone mineral density (BMD), and metabolic health. A previous report showed that pre-treatment testosterone (T) levels of <200 ng/dL is associated with greater improvement in spine BMD with T therapy. However, to date, there is no study investigating whether baseline T levels also influences body composition and metabolic response to T therapy. Objective: To determine if there are differences in the changes in body composition, metabolic profile, and bone turnover markers, in addition to BMD, in response to T therapy in men with baseline T level of < 264 ng/dL compared to those with levels \geq 264ng/dL Methods: Secondary analysis of single-arm, open-label clinical trial (NCT01378299) on pharmacogenetics of response to T therapy conducted between 2011-2016 involving 105 men (40-74 years old), with average morning T <300 ng/dL, given intramuscular T cypionate 200 mg every 2 weeks for 18 months. Subjects were divided into those with baseline T levels of < 264 ng/dL (N=43) and those with \geq 264 ng/dL (N=57). T and estradiol (E2) were measured by liquid chromatography/mass spectrometry; serum bone turnover markers (C-telopeptide [CTX], osteocalcin, sclerostin), adiponectin, and leptin by enzyme-linked immunosorbent assay; glycated hemoglobin (HbA1c) by high-performance liquid chromatography, areal BMD, and body composition by dual-energy x-ray absorptiometry (DXA). **Results:** Men with T < 264 ng/dL showed greater increases in total fat-free mass (FFM) at 18 months compared to those with T \geq 264 ng/dL (4.2±4.1 vs 2.7±3.8%; p=0.047) and unadjusted appendicular FFM at 6 and 18 months $(8.7\pm11.5 \text{ vs } 4.4\pm4.3\%, 7.3\pm11.6 \text{ vs } 2.4\pm6.8\%;$ p=0.033 and p=0.043, respectively). Men with $T \ge 264$ ng/ dL showed significant decreases in HbA1c at 12 months (-3.1±9.2 vs 3.2±13.9%; p=0.005), fasting glucose at 18 months (-4.2±31.9 vs 13.0±57.3%; p=0.040), LDL at 6 months (-6.4 ± 27.5 vs $12.8\pm44.1\%$; p=0.034), leptin at 18 months (-40.2±35.1 vs -27.6±31.0%; p=0.034) compared to those with T < 264 ng/dL. No significant differences in BMD and bone turnover markers were observed. **Conclusion:** T therapy results in improvement in body composition irrespective of baseline T levels but T <264 ng/dL is associated with greater improvement in FFM, whereas T level of \geq 264 ng/dL favors improvement in metabolic profile.

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