TPS12138 Poster Session

Testosterone replacement therapy for fatigue, sexual dysfunction, and quality of life in older men with cancer (TEMEC).

Egidio Del Fabbro, Shehzad Basaria, Donna L Berry, Thomas Storer, Tom Travison, Jose M. Garcia; Medical College of Georgia, Augusta, GA; Brigham and Women's Hospital, Boston, MA; University of Washington School of Nursing, Seattle, WA; Brigham and Women's Hospital, Boston, MA; Marcus Institute for Aging Research, Harvard Medical School, Boston, MA; United States Department of Veterans Affairs, Seattle, WA

Background: Fatigue is prevalent in men with cancer, affecting 70-100% of survivors. Fatigue impairs quality of life (QOL), increases caregiver burden, and is associated with reduced lean body mass and sexual dysfunction. Muscle loss, fatigue, sexual dysfunction and depressed mood are common in older males with testosterone deficiency, with or without cancer. Testosterone replacement therapy (TRT) in non–cancer patients improves fatigue, body composition and sexual function. However, despite high prevalence of testosterone deficiency in men with cancer (50-90%), no TRT practice guidelines are available. Older age, chronic inflammation, opioids, megestrol acetate, corticosteroids and some anti-neoplastic therapies are implicated in lowering testosterone. A preliminary (n=29) double blind trial comparing 4 weeks of intramuscular (n=13) TRT to placebo (n=16) in men with advanced cancer reported improvement in fatigue and sexual desire scores. Based on these findings, TRT may mitigate fatigue and related symptoms but requires a large, adequately powered trial. **Methods:** Randomized, double-blind, placebo-controlled trial of daily transdermal testosterone or placebo gel for 6-months in men ≥55 years, with solid or hematological cancer. Participants with no evidence of disease or receiving anti-neoplastic therapy are eligible if they report fatigue, have low serum testosterone by mass spectrometry <348 ng/dl or free testosterone <70 pg/ml and the interval from last treatment (chemotherapy, radiation therapy, immunotherapy), is ≤60 months. Ineligibility includes prostate cancer, elevated PSA, hematocrit >48% or recent thromboembolism. Sample size is predicated on 1:1 randomization to two arms, stratified by 3 sites and 90% power to detect relevant effects. Assignment of participants to either testosterone or placebo via permuted block design is known to statistician, study pharmacists, and unblinded study physician responsible for dose-adjustment. By December 2024, 150 of planned 230 participants are enrolled. NCT04301765. Primary outcome is change in fatigue by Functional Assessment of Chronic Illness Therapy fatigue scale (FACIT-Fatigue). Secondary outcomes include Harbor-UCLA 7-day Sexual Function Questionnaire including sexual activity and desire. Additional outcomes include questionnaires of erectile function, positive and negative affect scale (PANAS), Brief Assessment Scale determining Caregiver Burden (BASC) and body composition by dual energy X-ray absorptiometry. Physical performance evaluations include maximal leg press strength, 6-minute walk test and actigraphy. Additionally, lived experiences of 60 participants at baseline and 24 weeks are assessed by semi-structured, qualitative phone interviews with men from testosterone and placebo arms. Clinical trial information: NCT04301765. Research Sponsor: National Institute on Aging; AG061558.