Introduction: As the prevalence of male hypogonadism (HG) has increased, more patients are prescribed TRT. TRT may be associated with an increased risk of deep venous thrombosis (DVT). Although in recent years there have been more studies dedicated to adverse effects of TRT, the literature is mixed on whether TRT increases the risk of DVT.
Objective: This study evaluates the risk of developing DVT in men with hypogonadism based on which types of treatments trends they receive using the MarketScan insurance claims database.
Methods: We performed a retrospective analysis of the IBM MarketScan™ Commercial Claims and Encounters database between 2008-2017. We identified all men with an HG diagnosis using the International Classification of Disease 9th edition (ICD-9) or 10th edition (ICD-10). We recorded how often they received TRT (including formulations as oral, topical/transdermal gels/creams/patches, intranasal, injections, and pellet implants). We followed men to see how many were diagnosed with DVT or pulmonary embolism. We excluded men who had a record of thromboembolic events before their first HG diagnosis. We performed univariate tests of variation across different demographics in three separate stratifications: 1) In all patients stratified by whether they suffered DVT; 2) In patients with DVT stratified by whether they received any kind of treatment at any time; 3) In patients with DVT and any treatment stratified by the type of treatment. Hazard Ratios from Cox Models were calculated for the effects of TRT in the previous 6 months on DVT controlling for the following confounding variables: age and comorbidities such as smoking, drug abuse, obesity, heart disease, cardiovascular problems and surgery/immobilization. Age and TRT in the previous 6 months were included as time-varying covariates.
Results: We identified 1,853,889 total men with HG, of which 21,414 (1.16%) were diagnosed with DVT. Among men who suffered DVT, 7,487 (34.96%) received TRT at some point compared to 605,534 (33.04%) of the men who did not suffer DVT. Results from time-varying Cox models suggest that receipt of TRT in the previous 6 months does not significantly increase the risk of developing a DVT (hazard ratio (HR) 1.049; 95% CI: 0.85, 1.29) among men with HG.
Conclusions: Our study suggests that TRT is not associated with a higher risk of developing DVT. DVT has evidence that the association was more pronounced among patients of later middle age and with chronic disease, whether with or without TRT. Further investigation is warranted to assess the risk effect of TRT on DVT development, which may allow for a more proactive approach in management.
Disclosure: No

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PERSISTENT TESTOSTERONE SUPPRESSION AFTER CESSATION OF ANDROGEN DEPRIVATION THERAPY FOR LOCALIZED PROSTATE CANCER

Delgado, J[1]; Ory, J[2,3]; Bitran, J[1]; Blachman Braun, R[1]; Nackeeran, S[1]; Ramasamy, R[1]
[1]University of Miami, Department of Urology, Miami FL; [2]University of Miami, Department of Urology, Miami FL; [3]Department of Urology, Dalhousie University, Halifax, Nova Scotia, Canada

Introduction: ADT plays a fundamental role in the treatment of localized prostate cancer. However, there is limited data regarding testosterone recovery in men who have received ADT for prostate cancer. Identification of T recovery profiles associated with ADTs will facilitate personalization of ADT regimens and guide future treatment strategies to minimize the risk of T deficiency in patients with prostate cancer.
Objective: Temporary use of Androgen Deprivation Therapy (ADT) is a cornerstone in the treatment of localized prostate cancer. However, the ability for testosterone to recover after ADT is not well understood. The aim of this study was to investigate testosterone recovery in men with prostate cancer following varying ADT modalities and treatment durations.
Methods: A global federated health research network (TriNetX) was used to identify men with a diagnosis of prostate cancer who underwent temporary use of ADT. Three cohorts were identified: Men who received LHRH antagonists, LHRH agonists, and men who received combined ADT (LHRH agonist and antiandrogens). Further stratification was based on treatment duration of 6 or 18 months to compare T recovery profiles at follow up periods of 2 and 5 years.
Results: A total of 17,884 men received LHRH agonists alone, 12,767 men received combined ADT, and 628 men received LHRH antagonist therapy alone. Eugondal mean baseline T level (>300 ng/dL) prior to starting ADT was an inclusion criterion for all men. Five years after ADT cessation, 36% of patients who received LHRH agonists recovered eugondal T levels, 26% recovered after LHRH antagonist therapy, and 36.8% recovered after combined ADT. Overall, more than half of men who received ADT failed to recover eugondal T levels even 5 years after treatment cessation.
Conclusions: Five years after ADT cessation, incomplete testosterone recovery persists in more than 50% of men. Testosterone deficiency will lead to metabolically adverse changes in body composition, increased insulin resistance, impaired bone health, and poor quality of life and needs to be evaluated even after cessation of ADT.
Disclosure: No

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UTILITY OF DIRECTLY MEASURED FREE TESTOSTERONE IN PREDICTING BENEFIT OF TESTOSTERONE THERAPY IN MEN WITH HYPOGONADAL SYMPTOMS AND NORMAL TOTAL TESTOSTERONE

Chandrasekaran, N[1]; Bustillos, P[2]; Starke, N[2]
[1]Texas A&M College of Medicine; [2]Methodist Urology Associates

Introduction: Hypogonadal symptoms, including decreased libido, erectile dysfunction, and decreased energy/fatigue, often related to a low total testosterone (TT) level, are common among aging men, affecting at least 20% of men age ≥ 45.(1) Testosterone exists in two main forms: bound to proteins (primarily SHBG and albumin) and largely inactive, and as unbound free testosterone (FT). Current guidelines from multiple professional associations advise clinicians to use the presence of hypogonadal symptoms along with low serum TT to determine the need for Testosterone Replacement Therapy (TRT). The use of FT levels to guide treatment has not been established. Equilibrium dialysis is the gold standard for measuring FT, but rarely used clinically due to practical limitations.(2,3) Many guidelines also discourage the use of commercially-available directly measured FT by analog enzyme immunoassay (EIA) due to variability and accuracy concerns.(3) Thus, in guideline-based practice, symptomatically hypogonadal men with normal TT levels but low EIA FT are not offered TRT, despite some evidence that these men may benefit from treatment.(2)
Objective: To examine the benefits and safety of TRT in men with hypogonadal symptoms who demonstrate a normal TT level but low directly measured FT, as measured by a single national lab company (LabCorp) using EIA.
Methods: The study is an analysis of prospectively-collected data for 63 consecutive men seen in our clinical practice with hypogonadal symptoms, normal TT (>265 ng/dL) and low FT (normal range 7.2-24.0pg/mL). All men began a standardized regimen of T-cypionate IM injections at a dose of 200mg every 2 weeks.(4) Men with prior TRT were excluded. Baseline blood tests were performed for TT, FT, E2, LH, PRL, CBC, and PSA. Follow up blood tests included TT, FT, E2, CBC, and PSA. Clinical response to TRT was based on documentation of improvement in hypogonadal symptoms, including ED as measured using the IIEF-5 questionnaire, as well as subjective patient reports of changes in libido, energy, etc.

Results: A total of 63 men with a mean age of 64.0 yrs. (range 34-86 yrs.) were included. Prior to TRT, mean TT was 375.3ng/dL (IQR [312.0-419.5]) and mean FT was 4.7pg/mL (3.9-5.8). At 3-month follow up, mean TT was 690.8 (420.8-883.8) and FT was 11.71 (7.4-14.1). Mean IIEF-5 score prior to TRT was 12.2 (5.0-19.8) and after TRT was 13.3 (5.8-21.3). Within the cohort, 85.4% reported subjective improvement in overall energy and libido after 3 months of TRT, with 59.4% of patients reporting significant improvement and 26% reporting mild but noticeable improvement. The remaining 14.6% reported minimal or no improvement. Nearly half reported improvement in erection function, assessed by IIEF-5 questionnaire. One patient (1.6%) developed de novo erythrocytosis, and three (4.8%) developed pathologic rise in PSA.
Conclusions: Our findings suggest that many men with hypogonadal symptoms, normal TT, and low EIA FT respond well to TRT, and that such treatment is safe. Until the creation of specific guidelines regarding use of FT to guide TRT treatment decisions, it may be of clinical benefit to treat men based on appropriate symptoms and low directly measured FT levels.
Disclosure: Any of the authors act as a consultant, employee or shareholder of an industry for: Boston Scientific

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ETHNIC UNDERREPRESENTATION IN VALIDATION OF FEMALE SEXUAL DYSFUNCTION QUESTIONNAIRES

Redmon, C; Alzweri, L
The University of Texas Medical Branch

Introduction: Female sexual dysfunction (FSD) is a significant cause of morbidity that affects an estimated 30-50% of women. FSD is characterized by conditions which cause distress in at least one area — desire, arousal, orgasm, or pain — and can be challenging to diagnose depending on the patient-provider relationship and/or individual levels of comfort in having such discussions. Several questionnaires have been developed over the past four decades to assess FSD. This repertoire of tools includes assessments of overall sexual function, quality of life, and specific dysfunctions (i.e., hypoactive sexual desire disorder).
Objective: The purpose of this review is to evaluate the ethnic representation of sample populations used in the studies to validate questionnaires used to assess FSD.
Methods: A literature search was performed to gather information on questionnaires that have been developed to assess FSD. Subsequent searches were targeted to obtain the published studies used to validate each tool. Collective averages from the combined ethnic data were compared to population data from US census data and healthcare workforce reports to evaluate epidemiologic diversity. Ethnicity data from each questionnaire were investigated longitudinally to evaluate trends in representation of these sample populations over the past 40 years.
Results: Nineteen questionnaires were evaluated for ethnic representation based on published validation studies. Each questionnaire was tabulated to include the domain(s) assessed, number of items in each questionnaire, validation sample population size and description, and available ethnicity breakdown for each questionnaire. The average ethnic representation of the questionnaires relative to the US general population and US female health care workforce, respectively, was: Caucasian (78.3% vs. 62.7% and 68.5%), African American (3.3% vs. 13.3% and 8.3%), Hispanic (2.3% vs. 16.0% and 9.6%), American Indian (0.0% vs. 0.8% and 0.3%), Asian (0.6% vs. 6.4% and 6.2%), and Other (0.7% vs. 0.7% and 1.4%).
Conclusions: FSD is a common condition affecting women and causes significant impacts on quality of life. Review of the sample populations used to validate the questionnaires used to evaluate FSD in routine practice shows underrepresentation of ethnic minorities when compared to general population demographics. FSD questionnaire is an important research tool, helps increase health care providers and patients awareness of FSD, in addition, eventually improving access to care for ethnic minority women.
Disclosure: No

Table 1. Ethnic Representation in Validation of Female Sexual Dysfunction Questionnaires

	DSFI[18]	GRISS[19]	BISF-W[20]	SAQ-F[21]	CSFQ[22]	DISF[23]	FSFI[24, 25]	SFQ[26]	SLQQ[27]
Domains Assessed	Information, experience, drive, attitudes, psychological symptoms, affects, gender role definition, fantasy, body image, satisfaction	Females: Anorgasmia, vaginismus, avoidance, non-sensuality, dissatisfaction. Overall: frequency, non-communication	Overall sexual function, thoughts/desire, arousal, frequency of activity, receptivity/initiation, pleasure, satisfaction	Activity, frequency, habit, pleasure, discomfort	Desire, frequency, interest, pleasure, arousal, orgasm	Cognition/fantasy, arousal, behavior/experience, orgasm, drive/relationship	Desire, arousal, lubrication, orgasm, satisfaction, pain	Desire, arousal-sensation, arousal-lubrication enjoyment, orgasm, pain, partner relationship	Overall, QoL, treatment satisfaction
# Items	29	28	22	23	35	25	19	34	19
Sample (N)	213	88	269	528	155	399	259	1160	362
Description of Validation Population	Female heterosexual controls and subjects with sexual dysfunction	Men and women from sex therapy clinics throughout UK	Healthy women and surgically menopausal women	Women with strong family history of breast cancer (recruited to tamoxifen trial) and no family history of breast cancer (from community) in London	Medical students and psychiatry residents	Community sample of males and females	Controls and age-matched subjects with female sexual arousal disorder	Premenopausal and postmenopausal women on ERT, postmenopausal women without ERT with diagnosis of FSD	Patients from US Urology clinics with erectile dysfunction and their partners
Ethnic Profile									
Caucasian	82.2%		95.8%			93.4%	76.4%	97.0%	
African American	16.8%		1.9%			-	11.2%	balance	
Hispanic	-		1.9%			-	7.7%	-	
American Indian	-		-			-	0.4%	-	
Asian	-		0.4%			-	3.5%	balance	
Other	-		-			-	0.8%	balance	
Year Published	1976	1986	1994	1996	1997	1997	2000	2002	2002

‚Ethnicity profile adapted to reflect females included in the validation study

Table 1. Ethnic Representation in Validation of Female Sexual Dysfunction Questionnaires (continued)

	FSDS[28]	FSDS-R[28]	SSS-W[29]	ASEX[30]	SADI[31]	SIDI-F[32]	CSFQ-14[33]	CSDS[34]	WSID-SF[35]	DSDS[36]
Domains Assessed	Overall	Overall	Contentment, communication, compatibility, relational concern, personal concern	Overall, drive, arousal, lubrication, orgasm, satisfaction	Arousal, desire, motivation, aversion	Hypoactive sexual disorder, female orgasmic disorder	Pleasure, frequency, interest, arousal, orgasm, desire	Arousal, desire, esues	Distress, arousal, partner relationship	Desire, distress
# Items	12	13	30	5	54	13	14	40	9	5
Sample (N)	174	247	181	57	235	90	4514	138	629	1560
Description of Validation Population	Premenopausal and postmenopausal women with female sexual arousal disorder in randomized clinical trial of pharmacological therapy	Women with hypoactive sexual disorder age-matched with women from community	Participants recruited via local radio/news advertisements	Hospital employees, staff, residents, and faculty at University of Arizona (controls) and psychiatric patients	Male and female Canadian university students		Medical students and psychiatry residents, women attending Midlife Health Clinic, men and women diagnosed with MDD	Community sample of women with FSD and age-matched controls	Postmenopausal women with and without HSDD	Premenopausal ROSE trial participants (US & Canada) and ORCHID trial participants (11 European countries) complaining of distress due to decreased sexual desire
Ethnic Profile										
Caucasian	87.0%		75.1%	92.3%		78.9%	93.6%	71.7%	86.5%	90.3%
African American	-		4.4%	-		20.0%	2.8%	3.6%	12.7%	3.4%
Hispanic	-		10.5%	-		-	2.7%	15.2%	-	4.9%,
American Indian	-		0.6%	-		-	-	-	0.5%	-
Asian	-		4.4%	-		1.1%	0.3%	6.5%	0.2%	0.7%
Other	-		5.0%	-		-	0.8%	2.9%	0.2%	0.7%
Year Published	2002	2002	2005	2005	2006	2006	2006	2006	2010	2013

‡includes "White Hispanic" and "Asian Hispanic", reflects "Missing" classification from validation study

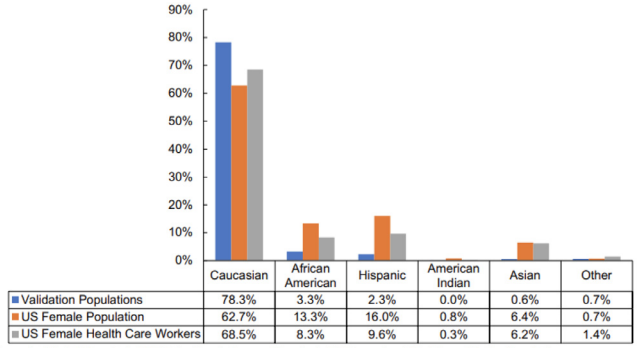

Figure 1. Ethnic Diversity in Validation Populations vs. Females in US General and Healthcare Worker Populations.

Comparison of average representation by ethnic category for validation populations (weighted), US female general population based on 2019 Census data, and US female healthcare workers based on workforce data reports.