Androgen Society

The Androgen Society 6th Annual Meeting

ABSTRACT BOOK

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Androgen Society

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Increase in testosterone measurements and doses of testosterone replacement therapy reimbursed by the Belgian Healthcare system between 2013 and 2022

Androgen Society Meeting 2024

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Objective: Regional differences in prescription patterns of testosterone replacement therapy (TRT) and testosterone measurements exist, with an increase in testosterone prescriptions reported in several countries. We investigated temporal changes in testosterone testing and reimbursed doses of TRT covered by the Belgian healthcare system.

Methods: Anonymous data on testosterone and SHBG measurements and on TRT were requested from the government for 2012-2022, which covers reimbursed pharmaceutical preparations, prescribed by a physician and provided via public pharmacies. In Belgium, only Sustanon® is reimbursed, so this dataset doesn't contain data on transdermal preparations or testosterone undecanoate. One package of Sustanon® sold in Belgium contains 250 mg testosterone esters.

Results: In 2013, total testosterone was measured 105.060 times in Belgian adult men. This increased to 149.602 in 2022 (+42%). The amount spent by the healthcare system for testosterone testing increased from €379.394 in 2013 to €551.759 in 2022 (+45%). SHBG was measured 48.442 times in 2013 and increased to 70.715 in 2022 (+46%), with the amount spent by the healthcare system increasing from €155.547 in 2013 to €231.876 in 2022 (+49%). In 2013, 37.950 doses of Sustanon® were sold to adult men. In 2022, this increased to 76.189 doses (+101%), corresponding to a cost of €373.330 in 2013 and €675.042 in 2022 (+81%). To put these numbers into perspective, from 2013 till 2022, the number of Belgian adult men increased by 5.8% (4.3 million in 2013 and 4.6 million in 2022). Inflation was 28.5% over 10 years.

Conclusions: The number of testosterone measurements increased by 42% in Belgium between 2013 and 2022. Remarkably, the number of doses of the only reimbursed TRT preparation showed an increase of 101%, which is much larger compared to the number of testosterone measurements. These findings correspond to similar trends of prescription pattern increases reported in other European countries.

Titratable Oral Testosterone Undecanoate Achieved Similar Testosterone Levels Across BMI Subgroups

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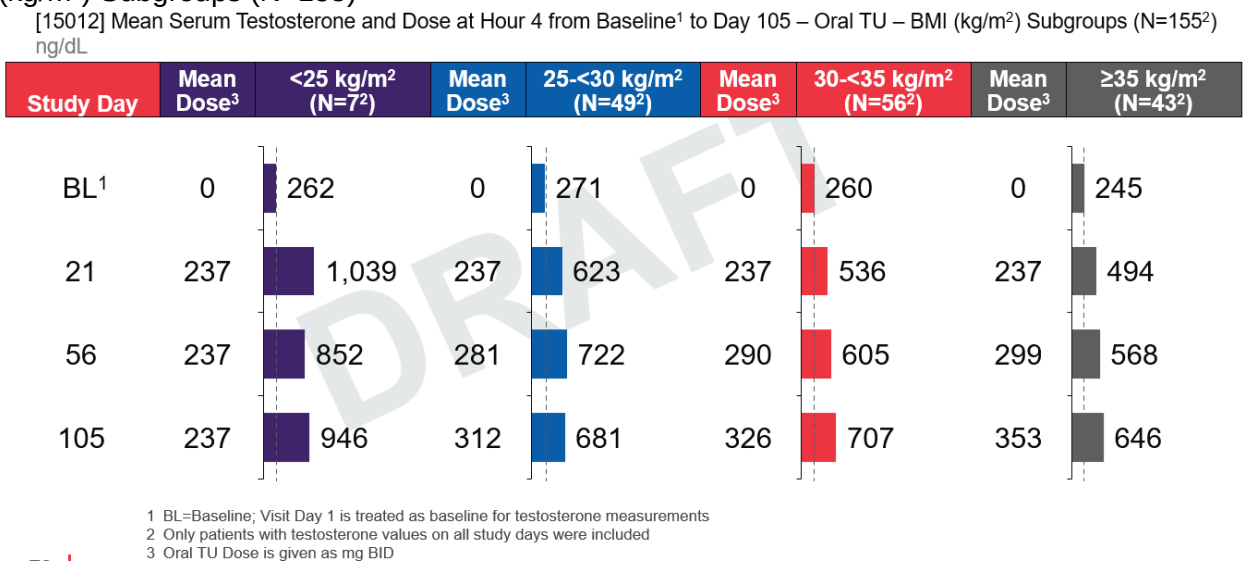
Introduction: >2.4 million US men have hypogonadism[1], defined as serum testosterone (T) <300ng/dL[2]. Negative effects associated with hypogonadism include development of metabolic syndrome[3], increased risk of coronary artery disease[4], and decreased libido[5]. Oral T replacement therapies provide a route of administration that may be more appropriate for some patients' needs. As not all patients are the same and do not metabolize drugs the same way, the ability to titrate oral T replacement therapies may be beneficial. We present analyses from a phase 3 study of testosterone undecanoate (TU) to explore the relationship between body mass index (BMI) and T levels achieved.

Methods: A phase 3, randomized, active controlled, open-label study was conducted to assess the safety and efficacy of oral TU in 222 hypogonadal men. The initial oral TU dose was 237mg TU BID. Titration adjustments were made on Day 35 and 70 based on the 24-hour average T concentration on day 21 and 56. BMI subgroups were <25, 25-<30, 30-<35, and ≥35 kg/m^2.

Results: Mean T at 4 hours post-dose by BMI subgroups are shown in Figure 1. Mean TU doses on day 105 were 237, 312, 326 and 353 mg for <25, 25-<30, 30-<35, and ≥35 kg/m^2 BMI subgroups, respectively (Figure 1). Percentage of patients who required 0, 1, or 2 titrations were 25%, 34%, and 41%, respectively.

Conclusions: Overall, oral TU achieved similar T levels across BMI subgroups with higher BMI patients utilizing higher doses. Men may likely require different T doses based on factors such as BMI to achieve effective levels. Therefore, an oral T replacement therapy that allows for dose titration would likely be preferable to a fixed dose.

Figure 1: Mean Serum Testosterone and Dose at Hour 4 From Baseline to Day 105 by BMI (kg/m^2) Subgroups (N=155)



1 BL=Baseline; Visit Day 1 is treated as baseline for testosterone measurements
2 Only patients with testosterone values on all study days were included
3 Oral TU Dose is given as mg BID

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5. Emily Sexson, J.K., *Male Hypogonadism: A Review of the Disease and Its Treatment*, in *US Pharm*. 2010. p. HS7-HS16

Professional Biography

Dr. Khera earned his undergraduate degree at Vanderbilt University. He subsequently earned his Masters Degree in Business Administration and his Masters Degree in Public Health from Boston University. He received his Medical Degree from The University of Texas Medical School at San Antonio and completed his Urology residency training in the Scott Department of Urology at Baylor College of Medicine.

At Baylor, he completed a one-year general surgery internship and then went on to complete a five-year residency program in Urology. After completing his Urology residency, he went on to complete a one-year fellowship in Male Reproductive Medicine and Surgery at Baylor. Currently, he is a Professor in the Scott Department of Urology at Baylor College of Medicine, and he holds the F. Brantley Scott Chair in Urology. Dr. Khera specializes in male and female sexual dysfunction, Men's Health, and hormone

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Dr. Khera also serves as the Director of the Laboratory for Andrology Research, the Medical Director of the Baylor Executive Health Program, and the Medical Director of the Scott Department of Urology. He also serves as President of the Sexual Medicine Society of North America.

Weight Loss in Men with Functional Hypogonadism and Obesity on Long-Term Testosterone Therapy

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Introduction:
Testosterone therapy (TTh) is addressed in AACE Guidelines as an approach to treating obesity in hypogonadal men. We investigated effects of TTh over 14 years.

Methods:
In a registry of men with hypogonadism, 503 men had functional hypogonadism and obesity. 299 men received testosterone therapy (TTh) by testosterone undecanoate (TU) injections 1000mg/12weeks following an initial 6-week interval (T-group). 204 men opted against TTh and served as controls (CTRL). Mean values are reported, and changes over time between groups, adjusted for age, weight, waist circumference, fasting glucose, blood pressure, lipids and quality of life to account for baseline differences between groups. To further reduce the impact of confounding factors, propensity matching (PM) for baseline age and waist circumference (WC) was performed.

Results:
Propensity matching resulted in 190 pairs.

Mean age at baseline: 59.2±6.4 years (T-group-all) and 62.5±5.6 (CTRL-all), 62.1±4.4 (T-group-PM), 62.2±5.6 (CTRL-PM).

Mean (median) follow-up: T-group 10.8±3.3 (12), CTRL 9.8±3.6 (10) years.

Waist circumference (cm) decreased from 115.8±13.9 to 97.0±4.5 (T-group-all) and increased from 119.2±12.2 to 122.6±5.9 (CTRL-all). Estimated adjusted difference between groups at 14 years: -24.7 [95% CI: -25.8;-23.6]. In the PM-groups, WC decreased from 117.8±14.0 to 98.3±4.3 (T-group-PM)

and increased from 119.2±12.0 to 122.7±6.2 (CTRL-PM), difference between groups at 14 years: -25.5 [95% CI: -26.9;-24.1] (p<0.0001 for all).

Weight (kg) decreased from 114.8±11.8 to 86.6±6.5 (T-group-all) and increased (CTRL-all) from 106.1±10.9 to 109.1±5.5. Difference between groups: -33.8 [95% CI: -35.4;-32.3]. In the PM-groups, weight decreased from 116.9±11.4 to 88.2±6.4 (T-group-PM) and increased from 106.0±10.9 to 109.0±5.6 (CTRL-PM), difference between groups at 14 years: -35.2 [95% CI: -37.0;-33.4] (p<0.0001 for all).

BMI (kg/m²) decreased from 36.9±3.6 to 28.1±2.0 in the (T-group-all) and increased from 34.1±3.4 to 35.3±1.9 (CTRL-all). Difference between groups: -10.9 [95% CI: -11.4;-10.4]. In the PM-groups, BMI decreased from 37.5±3.6 to 28.5±2.1 (T-group-PM) and increased from 34.1±3.4 to 35.4±1.9 (CTRL-PM), difference between groups at 14 years: -11.3 [95% CI: -11.9;-10.7] (p<0.0001 for all).

Weight change from baseline was -23.3±4.8% (T-group-all) and 9.7±2.7% (CTRL-all). Difference between groups: -31.3% [95% CI: -32.6;-30.1]. In the PM-groups, weight change from baseline was -24.9±4.5% (T-group-PM) and 9.6±2.8% (CTRL-PM), difference between groups at 14 years: -32.1% [95% CI: -33.6;-30.6] (p<0.0001 for all).

Conclusion:
Men with functional hypogonadism and obesity receiving TTh experienced clinically meaningful, sustained weight loss over 14 years. Untreated men gained weight.

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Curriculum Vitae

1992 born in Bremerhaven, Germany; currently training in a private medical office, 2019 – 2025 residency in urology, 2012 – 2019 studies of human medicine; 2004 start of registry study on long-term testosterone therapy with TU.

Karim Sultan Haider has authored and co-authored more than 25 peer-reviewed papers and more than 150 scientific abstracts.

Long-term testosterone therapy in men with functional hypogonadism is associated with improved sexual function and quality of life

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Introduction:
Sexual function is closely associated with quality of life (QoL). We investigated long-term effects of testosterone therapy (TTh) in men with functional hypogonadism.

Methods:
In a registry study, 824 men with functional hypogonadism were followed for a maximum time of 15 years. 409 men received testosterone undecanoate injections 1000 mg/12 weeks following an initial 6-week interval (T-group), 415 opted against TTh and served as controls (CTRL). Changes over time between groups were compared and adjusted for age, weight, waist circumference, fasting glucose, blood pressure, lipids and quality of life to account for baseline differences between the two groups. International index of erectile function – erectile function domain (IIEF-EF) and sexual frequency per month were assessed at every visit.

Results:
Baseline age was 57.7±7.0 years in the T-group and 62.7±5.3 years in CTRL ($p<0.0001$). Mean follow-up was 11.6±3.4 years in the T-group and 11.8±3.4 in CTRL. Median follow-up was 12 years in the T-group and 13 years in CTRL.

At baseline, PDE5-Inhibitors were used by 28.9% of men in the T-group and by 21.7% in CTRL ($p<0.05$).

Baseline IIEF-EF was 17.0±5.9 (mild to moderate) in the T-group and 19.6±3.7 (mild to moderate) in CTRL ($p<0.0001$). In the T-group, IIEF-EF increased to 29.4±1.0 (no ED) in year 15 ($p<0.0001$). In CTRL, IIEF-EF decreased to 6.7±0.8 (severe ED) in year 15 ($p<0.0001$). The estimated

adjusted difference between groups was 26.1 [95% CI: 25.4;-26.9] (p<0.0001).

Baseline self-reported sex frequency per month was 3.6±1.3 mL in the T-group 8.2±3.2 in CTRL (p<0.0001). In the T-group, sex frequency increased to 9.9±1.7 in year 15 (p<0.0001). In CTRL, sex frequency decreased to 0.0±0.0 in year 15 (p<0.0001). Estimated adjusted difference between groups: 14.9 [95% CI: 14.0;15.8] (p<0.0001).

QoL, assessed by the Aging Males' Symptoms scale (AMS), improved from 53.8±9.8 (severe symptoms) to 17.3±0.5 (no symptoms) in the T-group and worsened from 40.7±5.8 (moderate symptoms) to 67.0±5.9 (severe symptoms) in CTRL. The estimated adjusted difference between groups at 15 years was -55.2 [95% CI: -56.7;-53.8] (p<0.0001 for all).

Conclusion:
In men with functional hypogonadism, long-term TTh was associated with sustainably improved sexual function over 15 years. This may have contributed to improvements in QoL. In the untreated control group, sexual function and QoL deteriorated.

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Curriculum Vitae

1992 born in Bremerhaven, Germany; currently training in a private medical office, 2019 – 2025 residency in urology, 2012 – 2019 studies of human medicine; 2004 start of registry study on long-term testosterone therapy with TU.

Karim Sultan Haider has authored and co-authored more than 25 peer-reviewed papers and more than 150 scientific abstracts.

Long-term testosterone therapy (TTh) may improve insulin sensitivity in men with hypogonadism and type 2 diabetes (T2DM) never receiving insulin treatment in an observational registry study

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Introduction:
To investigate effects of TTh on insulin sensitivity, patients with hypogonadism and T2DM never exposed to exogenous insulin were analysed.

Methods:
Of 198 men with hypogonadism and T2DM, 104 received testosterone undecanoate injections 1000 mg/12 weeks following an initial 6-week interval (T-group), 94 opted against treatment (CTRL). Oral glucose tolerance tests (OGTT) were performed annually at the local diabetes center. Means and standard deviations over 14 years of treatment are reported.

Results:
Mean baseline age: 58.8±7.4 (T-group) and 62.2±4.9 (CTRL) ($p<0.0001$), median follow-up: 10 (T-group) and 11 years (CTRL).

C-peptide (mg/dL): Baseline C-peptide decreased from 3.6±0.8 to 2.9±0.5 after 14 years (T-group) and increased from 3.5±0.5 to 7.9±1.4 (CTRL). 1hr C-peptide decreased from 9.9±2.4 to 7.7±1.3 (T-group) and increased from 9.7±1.5 to 22.1±4.8 (CTRL). 2hr C-peptide decreased from 16.7±4.0 to 2.9±0.5 (T-group) and increased from 16.8±2.3 to 37.9±7.3 (CTRL) ($p<0.0001$ for all).

Glucose (mg/dL): Baseline glucose decreased from 140.8±20.6 to 97.9±2.5 after 14 years (T-group) and increased from 114.6±13.6 to 146.2±21.6 (CTRL). 1hr glucose decreased from 212.4±13.2 to 167.7±21.8 (T-group) and increased from 195.4±15.4 to 229.2±25.7 (CTRL). 2hr glucose decreased from 195.5±36.4 to 134.7±3.1 (T-group) and increased from 205.9±19.0 to 251.7±31.3 (CTRL) ($p<0.0001$ for all).

Incremental AUC C-peptide decreased from 774±189 to 290±62 (T-group) and increased from 768±110 to 1754±380 (CTRL) ($p<0.0001$ for both).

Incremental AUC glucose decreased from 5931±2291 to 5290±1326 (T-group) and increased from 7589±627 to 8148±2044 (CTRL) ($p<0.0001$ for both).

Conclusions:
Results of OGTT incl. C-peptide as surrogate parameter of pancreatic insulin secretion suggest that, in men with hypogonadism receiving TTh, less insulin may be required for glucose control, suggesting a progressive insulin-sensitizing effect of testosterone.

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Curriculum vitae

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Effects of Long-Term Testosterone Therapy in Men with Hypogonadism and Type 1 Diabetes: Data from a Registry Study

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Introduction:
Compared to type 2 diabetes, there is no increased prevalence of hypogonadism in type 1 diabetes (T1DM).

Methods:
Of 898 men with hypogonadism in a German urological registry study, 21 men had T1DM and received testosterone undecanoate 1000 mg/12 weeks following an initial 6-week interval. All men received diabetes treatment in a local diabetes center. Means and standard deviations of absolute measures over 14 years are reported.

Results:
Mean baseline age: 54.9±4.3 years, mean (median) follow-up: 12.3±2.0 (13) years.

13 men were obese, 7 overweight, and 1 had normal weight. Waist circumference decreased from 101.9±7.7 to 89.3±4.1 cm, weight from 97.1±14.6 to 78.9±6.7 kg, BMI from 31.7±4.5 to 26.0±1.9 kg/m² ($p<0.0001$ for all).

Systolic blood pressure (BP) decreased from 156.4±15.4 to 131.0±4.9, diastolic BP from 91.7±9.4 to 73.6±2.3 mmHg ($p<0.0001$ for both).

Lipids (mmol/L): Total cholesterol decreased from 7.8±1.0 to 5.1±0.1, HDL increased from 0.9±0.2 to 1.7±0.2, LDL decreased from 4.2±1.0 to 2.3±0.3, triglycerides from 3.1±0.6 to 2.1±0.1 ($p<0.0001$ for all).

HbA1c decreased from 7.7±0.7 to 5.4±0.1%, fasting glucose from 6.5±0.7 to 5.4±0.1 mmol/L, and insulin dose from 56.0±3.8 to 10.6±10.4 U/L ($p<0.0001$ for all).

Erectile function, measured by the International Index of Erectile Function, improved from 18.7±5.8 (mild to moderate erectile dysfunction, ED) to 29.5±0.7 (no ED), and quality of life, measured by the Aging Males' Symptoms scale, from 50.8±11.0 (severe complaints) to 17.0±0.0 (no complaints)

There were neither deaths nor non-fatal myocardial infarctions or strokes.

Conclusions:
Long-term testosterone therapy in men with hypogonadism and type 1 diabetes improved metabolic-syndrome-related and quality-of-life-related parameters. It may be advisable to measure testosterone in men with type 1 diabetes if they present with symptoms and signs of hypogonadism.

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Curriculum vitae

1953 born in Alexandria, Egypt; 1973 – 1980 studies of human and veterinary medicine; 1990 – 1998 specialist for reproductive endocrinology, pediatric endocrinology, and andrology, Ferring GmbH, Kiel, Germany; 1998 – 2001 leader of clinical development andrology, Jenapharm, Jena, Germany; specialist in endocrinology of aging, male aging, male hormonal fertility control; 2001 – 2007 leader of product group "Male Health Care", Schering AG, Berlin, Germany; 2007-2019 Global Medical Affairs Andrology, Bayer AG, Pharmaceutical Division; 2019-2022 consultant to Bayer AG, Medical Affairs Andrology; since 2022 Global Medical Lead Nebido, Grunenthal GmbH, Aachen, Germany

Farid Saad has authored and co-authored more than 150 peer-reviewed papers and more than 700 scientific abstracts.

PRESENTATION TITLE

RELATION BETWEEN TIME OF PRESENTATION OF ERECTILE DYSFUNCTION (ED) AND SEARCH FOR INFORMATION ON THE INTERNET WITH IIEF-5 SEVERITY SCORE

AUTHORS

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ABSTRACT

Introduction: Our purpose is to assess the time between the onset of symptoms and the seeking of medical attention for Erectile Disfunction (ED). We hypothesize that patients with ED searching for information in unreliable sources increases time between symptoms onset and the first medical consultation.

Methods: A questionnaire was given to patients diagnosed with ED during urological consultation (June 2023 - March 2024). Questionnaire included questions about seeking information on the Internet, their findings, their source of information, their search motive, the date of onset of ED symptoms and the first time they went to a medical consultation for this reason. IIEF-5 questionnaire was applied to measure the severity of the ED, dividing it into 4 groups (mild, mild-moderate, moderate and severe).

Results: 120 questionnaires were collected. Of the patients, 3 (2.5%) had no ED, 29 (24.2%) had mild ED, 50 (41.7%) had mild-moderate ED, 29 (25.8%), 31 (25.8%) had moderate ED and 7 (5.8%) had severe ED. Average age was 46 years (22-82). Average time between the onset of symptoms and the first consultation was 25 months (0-178). 72 (60%) of the patients had previously searched for information on the Internet. There was a significant relationship with severity and internet search ($p<0.001$). We found a significant relationship between greater severity of ED and less time seeking medical treatment for the mild, mild-moderate and moderate groups ($p<0.001$, $p<0.001$, $p<0.001$). Severe ED group did not have a significant value ($p=0.09$). Patients who had previously searched for information on the Internet had a larger time to attend first consultation ($p<0.001$).

Eardley, I. **The Incidence, Prevalence, and Natural History of Erectile Dysfunction**. Sex Med Rev, 2013. 1: 3. Feldman, H.A., et al. **Impotence and its medical and psychosocial** correlates: results of the Massachusetts Male Aging Study. J Urol, 1994. 151: 54. Braun, M., et al. **Epidemiology of erectile dysfunction: results of the 'Cologne Male Survey'**. Int J Impot Res, 2000. 12: 305..

A Martin-Morales, **Specific aspects of erectile function in urology/andrology**,Int J Impot Res, 2004 Oct:16 Suppl 2:S18-25.

NA Pacenza, et al. **Utility of the 5-Item version of the International Index of Erectile function as a diagnostic tool for erectile dysfunction**., Prensa med. Arg 2005 92(8) 501-506

Conclusions: Patients had an average of 25 months among the onset of symptoms and the first medical consultation. Patients who had previously sought information on the Internet tend to go to consultation later. Patients with ED go to consultation sooner, except for the severe ED group.

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- A Martin-Morales, **Specific aspects of erectile function in urology/andrology**,Int J Impot Res, 2004 Oct:16 Suppl 2:S18-25.
- NA Pacenza, et al. **Utility of the 5-Item version of the International Index of Erectile function as a diagnostic tool for erectile dysfunction**., Prensa med. Arg 2005 92(8) 501-506

PROFESSIONAL BIOGRAPHY

Hector Rodrigo Gonzalez Carranza, MD

Medical surgeon interested in urology and sexual medicine, currently working at the Ángeles Metropolitano Hospital, in Mexico City.

Recognized with the CENEVAL award for EGEL performance of excellence. Diploma in Excellence in Medicine, as well as in Advanced Studies in Bioethics issued by the Anáhuac México University.
Winner of third place in free papers as co-author of the work "Management of penile fracture in the General Hospital of Mexico, prevalence and post-surgical repercussions on sexual function." In the National Congress of Urology LXXIV, of the Mexican Society of Urology, 2023.

Adjunct Testosterone Implant Therapy in Breast Cancer Patients

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Presentation abstract

Testosterone (T) is a woman's most abundant sex steroid hormone and vital to a woman's health, yet it is almost totally ignored by women's health care providers. When T was first isolated in 1935 it was quickly recognized that T could kill tissue cultures of breast cancer cells and T became the primary treatment for breast cancer in the 1940's and 50's. It was first FDA approved to treat breast cancer in 1952 and is currently FDA approved for palliative care of metastatic breast cancer.

This study is a IRB approved, prospective observational registry study comprised of breast cancer patients and survivors who have hormone deficiency symptoms and poor quality of life.

Cohort 1: Breast Cancer Patients who have completed initial treatment (surgery/chemo/radiation) and should be on endocrine therapy but are non-compliant due to side effects.

Cohort 2: Breast Cancer patients who have completed all standard of care therapy and have hormone deficiency symptoms and poor quality of life.

The presentation will include:
1. A review of the function of T in normal female physiology.
2. Historical review of the use of T in women's health and in breast cancer treatment.
3. Review the recent published research on the use of T in breast cancer prevention and treatment.
4. Review the safety of T use in Women.

This study started last year (2023) and is designed to have multiple co-investigators. We are seeking other providers that are interested in participating in the study.

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Dr. Woodford's Bio

H. Douglas Woodford, MD, FACOG

Dr. Woodford received his medical education and completed his internship and residency at the University of Tennessee-College of Medicine in Memphis, Tennessee. He has been in private practice in Florence, AL since 1985. He was Board Certified by the American Board of Obstetrics and Gynecology until he retired from OB/GYN in 2021. He is a Fellow of the American College of Obstetrics and Gynecology.

In 2009, Dr. Woodford began focusing more on his interests in bio-identical hormone therapy and nutrition. In 2012, he opened Full Life Wellness Center in Florence, where he focuses on pellet hormone therapy and integrative approaches to health and wellness. In 2022 he opened a branch of Full Life Wellness in Nashville, providing pellet HRT to women.

Dr Woodford became aware of medical literature showing that testosterone therapy can be safely used in women who have previously been treated for breast cancer. After breast cancer treatment many women suffer significant hormone deficiency symptoms but estrogen therapy is contraindicated. Dr Woodford along with a group of oncology partners are currently conducting an IRB approved clinical trial examining how testosterone pellet therapy may safely improve quality of life for breast cancer survivors.

Androgen Society

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