Low Testosterone: When to Test and When to Treat?

Megan Curtis, MD
Swedish First Hill Family Medicine
Objectives

• Review media and marketing portrayal of “low T” and testosterone therapy

• Recognize clinical indications to test for low testosterone

• Review the evidence for benefits and risks of testosterone therapy

*Scope: natal males with a history of normal puberty*
Two Case Scenarios

1. Elmer: 75 yo male c/o fatigue, poor libido, and “losing muscle”.

1. Chester: 50 yo male c/o loss of body hair, decreased testicular size, and fatigue.
“It’s not you... It could be Low T.”
The High Price of Low Testosterone

As a man ages, his hormones slacken, and that can drain his energy, sex drive, and ability. Science has an answer, and our guy injected it into his body. Should he keep doing it?

By Jeff Csatari
Thursday, January 2, 2014, 6:53 am
Manopause?!
Aging, insecurity and the $2 billion testosterone industry
BY DAVID VON DREHLE
Prescribing Practices: FDA

Advisory Committee Industry Briefing Document
Testosterone Replacement Therapy

Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

Meeting on September 17, 2014
Prescriptions in Men > 40 yo

0.8% (2001) → 3% (2011)

55,000 rx/mo (2000) → 550,000 (2014)

25-70% of patients have no baseline testosterone level

*FDA Advisory Committee Meeting on Testosterone Replacement Therapy, 2014*
Annual Testosterone Drug Revenue in the U.S.

2002: $324 million

2013: $2.4 billion

FDA Advisory Committee Meeting on Testosterone Replacement Therapy, 2014
Figure 8. Number of Prescriptions by Specialty

TRT TRx by Specialty
By Month: Jan 2000 - July 2014

TRT = testosterone replacement therapy, TRx = testosterone prescriptions, PCP = primary care physicians
Data source: IMS NPA [Projected TRx]
PCP totals include Family Practice, General Practice, Internal Medicine, and Osteopathic Medicine.

FDA Advisory Committee Meeting on Testosterone Replacement Therapy, September 17, 2014
Longitudinal Effects of Aging on Serum Total and Free Testosterone Levels in Healthy Men

S. MITCHELL HARMAN, E. JEFFREY METTER, JORDAN D. TOBIN, JAY PEARSON, AND MARC R. BLACKMAN

The Intramural Research Program, National Institute on Aging, National Institutes of Health (S.M.H., E.J.M., J.D.T., J.P.), and Department of Medicine (M.R.B.), The Johns Hopkins University School of Medicine, Baltimore, Maryland 21224

ABSTRACT

Many studies have shown cross-sectional (and two small studies, longitudinal) declines in total and/or free testosterone (T) levels, with age, in men. The extent to which decline in T is the result of the aging process suggested was artifactual, we observed significant, independent, age-invariant, longitudinal effects of age on both T and free T index (free T index = T/SHBG), with an average change of −0.124 nmol/L/yr and −0.039 nmol/L/yr SHBG Cm−1T, but not free T index, also decreased.
Baltimore Longitudinal Study of Aging

Figure 1: Effects of age and date on serum testosterone

Figure 3: Hypogonadism in aging men
The European Male Aging Study

Identification of Late-Onset Hypogonadism in Middle-Aged and Elderly Men

Frederick C.W. Wu, M.D., Abdelouahid Tajer, Ph.D., Jennifer M. Beynon, M.B.,
Stephen R. Pye, M.Phil., Alan J. Silman, M.D., Joseph D. Finn, B.Sc.,
Terence W. O’Neill, M.D., Gyorgy Bartfai, M.D., Felipe F. Casanueva, M.D., Ph.D.,
Gianni Forti, M.D., Aleksander Giwercman, M.D., Ph.D.,
Evan, M.D., Ph.D., Krzysztof Kula, M.D., Ph.D., Michael E.J. Lean, M.D.,
Ron, M.D., Margus Punab, M.D., Ph.D., Steven Boonen, M.D., Ph.D.,
Lars van der Schouw, M.D., Ph.D., Fernando Labrie, M.D., Ph.D.,
and Ilpo T. Huhtaniemi, M.D., Ph.D., for the EMAS Group

Hypothalamic-Pituitary-Testicular Axis Disruptions in Older Men Are Differentially Linked to Age and Modifiable Risk Factors: The European Male Aging Study

Frederick C. W. Wu, Abdelouahid Tajer, Stephen R. Pye, Alan J. Silman, Joseph D. Finn,
Terence W. O’Neill, Gyorgy Bartfai, Felipe F. Casanueva, Gianni Forti, Aleksander Giwercman,
Ilpo T. Huhtaniemi, Krzysztof Kula, Margus Punab, Steven Boonen, Dirk Vanderschueren, and The European Male Aging Study Group

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The European Male Aging Study

3500 men, 8 centers
The European Male Aging Study

3500 men, 8 centers

Hypogonadism: 3-5%
Male Aging ≠ hypogonadism

…..so what does define hypogonadism?
Hypogonadism – Endocrine Society Definition:

“We recommend making a diagnosis of androgen deficiency only in men with consistent symptoms and signs and unequivocally low serum testosterone levels.”
Non-specific signs/symptoms

- Low Energy
- Mood changes
- Concentration/memory
- Sleep disturbance
- Mild anemia
- Decreased muscle Mass
- Increased body fat, BMI
- Declining physical/work performance
Hypogonadism: Specific signs and symptoms

- Libido
- Loss of body hair
- Gynecomastia
- Decreased testicular size
- Vasomotor
- Bone density
- Sexual development
- Fertility
When to measure serum total testosterone: EARLY MORNING…

Snyder, PJ. Clinical Features and Diagnosis of Male Hypogonadism. UpToDate
When to measure serum total testosterone: EARLY MORNING... x2!

Snyder, PJ. Clinical Features and Diagnosis of Male Hypogonadism. UpToDate
### Table 21. Most Common Diagnosis Codes for Patients with a Testosterone Replacement Therapy Prescription (2006 to May 2014, N = 2,923,500)

<table>
<thead>
<tr>
<th>Diagnosis Code</th>
<th>Description</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>401.9</td>
<td>Unspecified essential hypertension</td>
<td>1,216,393</td>
</tr>
<tr>
<td>257.2</td>
<td>Other testicular hypofunction</td>
<td>1,196,709</td>
</tr>
<tr>
<td>272.4</td>
<td>Other and unspecified hyperlipidemia</td>
<td>1,191,424</td>
</tr>
<tr>
<td>780.79</td>
<td>Other malaise and fatigue</td>
<td>935,817</td>
</tr>
<tr>
<td>401.1</td>
<td>Benign essential hypertension</td>
<td>913,382</td>
</tr>
<tr>
<td>V70.0</td>
<td>Routine general medical examination at a health care facility</td>
<td>851,612</td>
</tr>
<tr>
<td>786.5</td>
<td>Unspecified chest pain</td>
<td>736,124</td>
</tr>
<tr>
<td>724.2</td>
<td>Lumbago</td>
<td>712,375</td>
</tr>
<tr>
<td>272</td>
<td>Pure hypercholesterolemia</td>
<td>683,196</td>
</tr>
</tbody>
</table>

Data source: SHA's Integrated Dataverse

Note: Common diagnosis codes could be biased by the incidence/prevalence of the condition.
Treating symptoms in the absence of hypogonadism…

… is using testosterone as an **anabolic steroid**.
"Testosterone treatment is not approved by the Food and Drug Administration to improve strength, athletic performance, appearance or normal problems associated with aging."
Primary vs. Secondary Hypogonadism

Snyder, PJ. Clinical Features and Diagnosis of Male Hypogonadism. UpToDate
Primary vs. Secondary Hypogonadism

Additional workup:
- LH
- FSH
- Prolactin
- TSH

→ Consider MRI

*Snyder, PJ. Clinical Features and Diagnosis of Male Hypogonadism. UpToDate*
<table>
<thead>
<tr>
<th>*Modifiable</th>
<th>Primary = Testicular</th>
<th>Secondary = hypothalamic/pituitary</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>[High FSH and LH]</td>
<td>[Low/normal FSH and LH]</td>
</tr>
<tr>
<td>Congenital</td>
<td>▪ Kleinfelter</td>
<td>▪ Idiopathic hypogonadotropic hypogonadism</td>
</tr>
<tr>
<td></td>
<td>▪ Undescended testes*</td>
<td>▪ Kallman syndrome</td>
</tr>
<tr>
<td>Acquired</td>
<td>▪ Opiates*</td>
<td>▪ Intracranial tumors</td>
</tr>
<tr>
<td></td>
<td>▪ Marijuana*</td>
<td>▪ Radiation/surgery to sellar region</td>
</tr>
<tr>
<td></td>
<td>▪ Testicular trauma</td>
<td>▪ Infiltrative/systemic illnesses</td>
</tr>
<tr>
<td></td>
<td>▪ Mumps orchitis</td>
<td>▪ Critical illness</td>
</tr>
<tr>
<td></td>
<td>▪ Radiation therapy</td>
<td>▪ Glucocorticoid therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Obesity*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Insulin resistance*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Androgen supplements*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Obstructive sleep apnea*</td>
</tr>
</tbody>
</table>
Address Modifiable Causes First

• Obesity, insulin resistance
• Cortisol/steroids
• Obstructive sleep apnea
• Opiates
• Marijuana
• Supplements/DHEA
Obesity and Sleep Apnea: More questions than answers

Obesity

Obstructive Sleep Apnea
Obesity and Sleep Apnea: More questions than answers

Obesity

- Hypogonadism
  - Insulin resistance
- Metabolic Syndrome

Obstructive Sleep Apnea
Obesity and Sleep Apnea: More questions than answers

- Obesity
- Hypogonadism
  - Insulin resistance
- Metabolic Syndrome
- Obstructive Sleep Apnea
Obesity and Sleep Apnea: More questions than answers

Obesity

Hypogonadism
- Insulin resistance
- Metabolic Syndrome

Obstructive Sleep Apnea

6/10/2016
WARNING – Underlying Illnesses Ahead

– Insulin resistance
– OSA
– Depression
– Hypothyroidism
– Substance abuse
– Erectile dysfunction
Weighing the Benefits and Risks with your Patients
Benefits*

- Libido
- Erectile function
- Hair growth
- Muscle vs fat mass
- Falls/physical functioning
- Mood
- Bone mineral density
- Fragility fractures
- Metabolic syndrome
- Cognition
- Insulin sensitivity
- Cardiovascular risk

*Most elicited through treatment of young, hypogonadal men (e.g. s/p orchiectomy)
Contraindications

- Breast or prostate cancer
- PSA > 4.0
- High risk for prostate cancer*
- Poorly controlled CHF
- Hct > 50
- Severe untreated OSA
- Desire for fertility
- Severe LUT symptoms
Adverse events, risks

- Erythrocytosis
- Acne, oily skin
- Overdiagnosis of subclinical prostate cancer
- Growth of metastatic prostate cancer
- Infertility, decreased sperm count
- Specific formulation concerns
Adverse events, risks

- Erythrocytosis
- Acne, oily skin
- Overdiagnosis of subclinical prostate cancer
- Growth of metastatic prostate cancer
- Infertility, decreased sperm count
- Specific formulation concerns

*Cardiovascular risk and death*
Reviewing Evidence for Risk

The NEW ENGLAND JOURNAL of MEDICINE

Adverse Events Associated with Testosterone Administration

Shehzad Basaria, M.D., Andrea D. Coviello, M.D., Thomas G. Trivison, Ph.D., Thomas W. Storer, Ph.D.,
Wildon R. Farwell, M.D., M.P.H., Alan M. Jette, Ph.D., Richard Eder, B.A., Sharon Tennstedt, Ph.D.,
Jagadish Ulloor, Ph.D., Anqi Zhang, Ph.D., Karen Choong, M.D., Kishore M. Lakshman, M.D.,
Norman A. Mazer, M.D., Ph.D., Renee Miceli, M.S., Joanne Krasnoff, Ph.D., Ayan Elmi, B.A., Philip E. Knapp, M.D.,
Brad Brooks, B.S., Erica Appleman, M.A., Sheetal Aggarwal, B.S., C.C.R.P., Geeta Bhasin, B.A.,
Leif Hedley-Brierley, Ashmeet Bhatia, M.B., B.S., Lauren Collins, R.N.P., Nathan LeBrasseur, Ph.D.,
Louis D. Fiore, M.D., and Shalender Bhasin, M.D.
Basaria et al.

- 200 community dwelling men ≥ 65 with mobility limitations randomized to testosterone gel or placebo gel for 6 months
- Trial stopped early due to increased CV risk in the treatment group
- CV risk was higher with polycythemia as well as higher testosterone levels
- Multiple limitations…
### Table 2. Baseline Characteristics Related to Cardiovascular Risk.\(^a\)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Testosterone (N = 106)</th>
<th>Placebo (N = 103)</th>
<th>P Value(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preexisting cardiovascular disease — no. (%)(^\d)</td>
<td>56 (53)</td>
<td>48 (47)</td>
<td>0.41</td>
</tr>
<tr>
<td>Obesity — no. (%)(^\d)</td>
<td>48 (45)</td>
<td>50 (49)</td>
<td>0.68</td>
</tr>
<tr>
<td>Blood pressure — mm Hg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>137±15</td>
<td>137±14</td>
<td>0.98</td>
</tr>
<tr>
<td>Diastolic</td>
<td>77±10</td>
<td>75±10</td>
<td>0.21</td>
</tr>
<tr>
<td>Hypertension — no. (%)(^\d)</td>
<td>90 (85)</td>
<td>80 (78)</td>
<td>0.21</td>
</tr>
<tr>
<td><strong>Antihypertensive therapy — no. (%)</strong></td>
<td>90 (85)</td>
<td>75 (73)</td>
<td><strong>0.04</strong></td>
</tr>
<tr>
<td>Diabetes mellitus — no. (%)(^\d)</td>
<td>25 (24)</td>
<td>28 (27)</td>
<td>0.63</td>
</tr>
<tr>
<td>Glycated hemoglobin — %</td>
<td>6.2±0.7</td>
<td>6.1±0.7</td>
<td>0.32</td>
</tr>
<tr>
<td>Lipids — mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>165±35</td>
<td>171±39</td>
<td>0.24</td>
</tr>
<tr>
<td>LDL</td>
<td>89±30</td>
<td>92±33</td>
<td>0.51</td>
</tr>
<tr>
<td>HDL</td>
<td>46±13</td>
<td>48±18</td>
<td>0.20</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>159±111</td>
<td>143±69</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Hyperlipidemia — no. (%)(^\d)</strong></td>
<td>67 (63)</td>
<td>51 (50)</td>
<td><strong>0.05</strong></td>
</tr>
<tr>
<td>Statin therapy — no. (%)</td>
<td>66 (62)</td>
<td>48 (47)</td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td>Framingham Risk Score — %**</td>
<td>22±6</td>
<td>21±6</td>
<td>0.31</td>
</tr>
<tr>
<td>Smoking status — no./total no. (%)</td>
<td></td>
<td></td>
<td>0.66</td>
</tr>
<tr>
<td>Never smoked</td>
<td>27/104 (26)</td>
<td>21/103 (20)</td>
<td></td>
</tr>
<tr>
<td>Former smoker</td>
<td>68/104 (65)</td>
<td>73/103 (71)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>9/104 (9)</td>
<td>9/103 (9)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Category</th>
<th>Total Risk</th>
<th>Instantaneous Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% CI)</td>
<td>Hazard Ratio (95% CI)</td>
</tr>
<tr>
<td></td>
<td>unadjusted</td>
<td>adjusted</td>
</tr>
<tr>
<td>MedDRA cardiac†</td>
<td>10.6 (1.3–84.5)</td>
<td>10.5 (1.3–82.4)</td>
</tr>
<tr>
<td>Atherosclerosis-related§</td>
<td>7.2 (0.9–59.7)</td>
<td>7.1 (0.9–57.8)</td>
</tr>
<tr>
<td>Cardiovascular-related¶</td>
<td>5.4 (2.0–14.9)</td>
<td>5.8 (2.0–16.8)</td>
</tr>
<tr>
<td>Dermatologic</td>
<td>2.6 (1.1–6.2)</td>
<td>4.9 (1.7–14.6)</td>
</tr>
<tr>
<td>Necessitating referral for medical evaluation</td>
<td>2.3 (0.98–5.3)</td>
<td>5.2 (1.8–14.6)</td>
</tr>
</tbody>
</table>

Table 4. Risk of Adverse Events with Testosterone Therapy, According to Category.*

* Adapted from Basaria et al. Adverse events associated with testosterone administration. N Engl J Med. 2010
Association of Testosterone Therapy With Mortality, Myocardial Infarction, and Stroke in Men With Low Testosterone Levels

Rebecca Vigen, MD, MScS1; Colin I. O’Donnell, MSc2,3; Anna E. Barón, PhD2,3; Gary K. Grunwald, PhD2,3; Thomas M. Maddox, MD, MSc2,4; Steven M. Bradley, MD, MPH2,3,4; Al Barqawi, MD2; Glenn Woring, MD2; Margaret E. Wierman, MD2,3; Mary E. Plomondon, PhD2,3,4; John S. Rumsfeld, MD, PhD2,3,4; P. Michael Ho, MD, PhD2,3,4
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Testosterone Treatment and Mortality in Men with Low Testosterone Levels

Molly M. Shores, Nicholas L. Smith, Christopher W. Forsberg, Bradley D. Anawalt, and Alvin M. Matsumoto

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Rebecca Vigen, MD, MSc3; Colin I. O’Donnell, MPh3; Alison M. Maddox, MD, MSc2,3,4; Steven M. Bradley, MD, MPh3; E. Wierman, MD2; Mary E. Pomeroy, PhD5,6; John Soper, MBBS2; Christopher W. Forsberg, MD7; Bradley D. Anawalt, MD, and Alvin M. Matsumoto, MD

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Veterans Affairs OAI/Broad Sound Health Care System, MMS, NLS, CWF, AMM, Seattle

Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men

William D. Finkle1, Sander Greenland2, Gregory K. Ridgeway1, John L. Adams1, Melissa A. Frasco1, Michael B. Cook3, Joseph F. Fraumeni Jr.3, Robert N. Hoover3

1 Consolidated Research, Inc, Los Angeles, California, United States of America, 2 Department of Epidemiology and Department of Statistics, University of California, Los Angeles, California, United States of America, 3 Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, Maryland, United States of America
Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials

Lin Xu¹, Guy Freeman¹, Benjamin J Cowling¹ and C Mary Schooling¹,²*

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¹Consolidated Research, Inc., Los Angeles, California, United States of America, ²Department of Epidemiology and Department of Statistics, University of California, Los Angeles, California, United States of America, ³Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, Maryland, United States of America
What about screening?
ADAM questionnaire about symptoms of low testosterone
(Androgen Deficiency in the Aging Male)

This basic questionnaire can be very useful for men to describe the kind and severity of their low testosterone symptoms.

1. Do you have a decrease in libido (sex drive)? Yes No
2. Do you have a lack of energy? Yes No
3. Do you have a decrease in strength and/or endurance? Yes No
4. Have you lost height? Yes No
5. Have you noticed a decreased "enjoyment of life" Yes No
6. Are you sad and/or grumpy? Yes No
7. Are your erections less strong? Yes No
8. Have you noticed a recent deterioration in your ability to play sports? Yes No
9. Are you falling asleep after dinner? Yes No
10. Has there been a recent deterioration in your work performance? Yes No

If you Answer Yes to number 1 or 7 or if you answer Yes to more than 3 questions, you may have low Testosterone.
So is there a role for screening?

Universally: NO

• There are few special populations to consider screening with history

• Asymptomatic → not hypogonadism

• Risk vs. benefit still unclear

• No trials show screening affects patient-oriented outcomes
Endocrine Society, 2010

“We recommend against screening for androgen deficiency in the general population.”

“We suggest that clinicians not use the available case-finding instruments for detection of androgen deficiency in men receiving health care for unrelated reasons.”
Special Populations
AUA Position Statement on Testosterone Therapy

“Testosterone therapy is appropriate treatment for patients with clinically significant hypogonadism, including those with idiopathic clinical hypogonadism that may or may not be age-related, after full discussion of potential adverse effects. Patients should understand that treatment requires follow-up and medical monitoring. Testosterone therapy in the absence of hypogonadism is inappropriate.”
Choosing Wisely®

An initiative of the ABIM Foundation

Endocrine Society

View all recommendations from this society

Released October 16, 2013*

Don’t prescribe testosterone therapy unless there is biochemical evidence of testosterone deficiency.
American Society for Reproductive Medicine

View all recommendations from this society

April 13, 2015

Don’t prescribe testosterone or testosterone products to men contemplating/attempting to initiate pregnancy.
American Society for Clinical Pathology

View all recommendations from this society

Released February 3, 2015

Don’t prescribe testosterone therapy unless there is laboratory evidence of testosterone deficiency.
American Urological Association

View all recommendations from this society

Released February 21, 2013; sources updated May 9, 2016

Don’t prescribe testosterone to men with erectile dysfunction who have normal testosterone levels.
The Bottom Line

“Low T” is a marketing ploy.

Low testosterone is a lab value.

Hypogonadism is a clinical diagnosis.
Take Home Points

• “Low T” ≠ hypogonadism

• Universal screening is not appropriate

• Evaluate for acquired/secondary causes

• Discuss benefits and risks of testosterone treatment with your patients

• Use a clinical guide for treatment


References


• Petteloud, N, Crowley, WF. Congenital Gonadotropin-releasing Hormone Deficiency (idiopathic hypogonadotropic hypogonadism). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 2, 2016).


References

• Snyder, PJ. Causes of Primary Hypogonadism in Males. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 2, 2016).

• Snyder, PJ. Causes of Secondary Hypogonadism in Males. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 2, 2016).

• Snyder, PJ. Clinical Features and Diagnosis of Male Hypogonadism. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 2, 2016).

• Snyder, PJ. Testosterone Treatment of Male Hypogonadism. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 2, 2016).


References


Colbert Report Video Clip