2018 AUA Guidelines: Testosterone Therapy Erectile Dysfunction

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Disclosures

• Consultant- AbbVie, Endo, Boston Scientific, Coloplast

• Research support- Boston Scientific
AUA Guidelines: Testosterone Therapy
AUA T Guidelines: Testing

- **Diagnosis**
  - TT < 300 ng/dL cutoff for T Def (Mod/B)
  - 2 different values; separate days; early am (Strong/A)
  - Low levels combined with clinical signs or symptoms (Mod/B)
  - Measure in select populations (men with unexplained anemia; loss BMD; DM; exposure to chemotherapy/radiation; HIV; chronic opiate use; male infertility; pit dysfunction; chronic corticosteroid use *even in the absence of clinical signs and symptoms*).

- **Adjuvant Testing**
  - Measure LH to clarify etiology (men may be eligible for SERMS) (Strong/A)
  - Measure prolactin levels in men with low T & low LH (pituitary MRI for T < 150 ng/dL in combination with low or normal LH even if prolactin levels normal).
AUA T Guidelines: Testing

• Serum estradiol should be measured in T Def patients who present with breast symptoms or gynecomastia prior to the commencement of TTh. (Expert Opinion)
  • Men who have elevated baseline estradiol measurements should be referred to an endocrinologist

• Prior to initiation of TTh, clinicians should measure hemoglobin and hematocrit and inform patients regarding the increased risk of polycythemia (Strong/A)

• PSA should be measured in men over 40 years of age prior to commencement of testosterone therapy to exclude a prostate cancer diagnosis. (Clinical Principle)
AUA T Guidelines: Treatment

• Adjust TTh dosing to achieve a total testosterone level in the middle tertile of the normal reference range (Cond/C) i.e. 450-600 ng/dL

• Clinicians should discuss the risk of transference with patients using testosterone gels/creams. (Strong/A)

• Clinicians may use aromatase inhibitors, human chorionic gonadotropin, selective estrogen receptor modulators, or a combination thereof in men with TTh desiring to maintain fertility (Cond/C)
Controversies?

FDA Label

Testosterone Guidelines

AUA 2018

Endocrine 2018
Venous Thromboembolism (VTE)
5.4 Venous Thromboembolism

There have been postmarketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products such as AndroGel 1%. Evaluate patients who report symptoms of pain, edema, warmth and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic event is suspected, discontinue treatment with AndroGel 1% and initiate appropriate workup and management [see Adverse Reactions (6.2)].
Venous Thromboembolism

AUA 2018 Guidelines

Patients should be informed that there is no definitive evidence linking testosterone therapy to a higher incidence of venothrombolic events (Moderate Recommendation; Evidence Level: Grade C)

Endocrine 2018 Guidelines

- No guideline statement
- “Case-control and pharmacoepidemiologic studies have not shown a consistent increase in the risk of venous thromboembolism (VTE) with T treatment. However, there are too few T-associated VTE events in RCTs to draw meaningful inferences.”
Cardiovascular Risk
Review of all articles from 1940-2014 relating to T and CVD

Over 200 articles identified

Only 4 articles suggesting increased CV risk with T

Several dozen studies demonstrated beneficial effects of normal T on CV risk and mortality

Low levels of T associated with increased risk of mortality and CVD (LOE IIa)

Severity of CAD inversely correlated with serum T levels (LOE IIa)
Studies Claiming TTh Causes CVD

**Basaria et al**
*NEJM 2010*
- RPCT frail elderly men
- 15 grams of testosterone
- CVD not an endpoint
- Treatment arm greater CV risks
- 5 vs 2 major CV events (ie MI)
- No difference if exclude CHF

**Finkle et al**
*PLoS One 2014*
- No randomization or placebo
- No control group or clinical info
- Health insurance database
- 90 days after start testosterone
- Pre-prescription MI rate 3.48/1000
- Post-prescription MI rate 4.75/1000

**Vigen et al**
*JAMA 2013*
- No randomization or placebo
- 2 major corrections
  - “Absolute risk” of MI (19.9 vs 25.7%) vs (21 vs 10%)
  - Exclusion of 1132 men
- RETRACTION 29 societies

**Xu et al**
*BMC 2013*
- Meta-analysis of CV events in 27 PC studies of >12 weeks
- Just 2 studies provided 1/3 of all CV events in T treat arm
- If exclude 2 studies CV events in T and placebo are identical
5.5 Cardiovascular Risk

Long term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. To date, epidemiologic studies and randomized controlled trials have been inconclusive for determining the risk of major adverse cardiovascular events (MACE), such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone compared to non-use. Some studies, but not all, have reported an increased risk of MACE in association with use of testosterone replacement therapy in men.

Patients should be informed of this possible risk when deciding whether to use or to continue to use AndroGel 1%.

European Medicines Agency (EMA) performed its own review and declined to add a new CV warning
T and CV studies from September 2014 to July 2017
23 studies (12 clinical trials, 11 observational studies)
Results:
• No study reported increased MACE with TTh
• Men whose T normalized with TTh had reduced risk of MI and death compared with men whose T levels failed to normalize
**Cardiovascular Risk**

**AUA 2018 Guidelines**

- Clinicians should inform testosterone deficient patients that low testosterone is a risk factor for cardiovascular disease. *(Strong Recommendation; Evidence Level: Grade B)*
- Prior to initiating treatment, clinicians should counsel patients that, at this time, it cannot be stated definitively whether testosterone therapy increases or decreases the risk of cardiovascular events (e.g., myocardial infarction, stroke, cardiovascular-related death, all-cause mortality). *(Moderate Recommendation; Evidence Level: Grade B)*
- Testosterone therapy should not be commenced for a period of three to six months in patients with a history of cardiovascular events. *(Expert Opinion)*

**Endocrine 2018 Guidelines**

- We recommend against testosterone therapy in men with.... heart failure, myocardial infarction or stroke within the last 6 months… *(Low quality evidence)*
- “…there is no conclusive evidence that T supplementation is associated with increased cardiovascular risk in hypogonadal men.”
- “Thus, there are insufficient data to establish a causal link between T therapy and cardiovascular events.”
Indications for Testosterone Therapy
"Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

a) Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.

b) Hypogonadotropic hypogonadism (congenital or acquired)—idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation."
FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use

This information is an update to the FDA Drug Safety Communication: FDA Evaluating Risk of Stroke, Heart Attack, and Death with FDA-Approved Testosterone Products issued on January 31, 2014.

Safety Announcement

[03-03-2015] The U.S. Food and Drug Administration (FDA) cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man’s symptoms seem related to low testosterone. We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.
1 INDICATIONS AND USAGE

AndroGel 1% is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy. Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.

- Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.
Indications

AUA 2018 Guidelines
The clinical diagnosis of testosterone deficiency is only made when patients have low total testosterone levels combined with symptoms and/or signs (Moderate Recommendation; Evidence Level: Grade B)

Endocrine 2018 Guidelines
We recommend diagnosing hypogonadism in men with symptoms and signs of testosterone deficiency and unequivocally and consistently low serum total testosterone and/or free testosterone concentrations (when indicated) (Moderate quality evidence)
Prostate Cancer and BPH
5.1 Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer

- Patients with BPH treated with androgens are at an increased risk for worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms.
- Patients treated with androgens may be at increased risk for prostate cancer. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens [see Contraindications (4), Adverse Reactions (6.1) and Nonclinical Toxicology (13.1)].

“Contraindications” Section

- AndroGel 1% is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate [see Warnings and Precautions (5.1), Adverse Reactions (6.1), and Nonclinical Toxicology (13.1)].
# T and BPH Studies

## Table 1

Outcomes of studies assessing the effect of TRT on the Prostate/LUTS

<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th># of Patients</th>
<th>Follow-up</th>
<th>Design</th>
<th>Data Followed</th>
<th>Therapy</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emmelot-Vonk et al.,</td>
<td>The Netherlands</td>
<td>207</td>
<td>6 mo</td>
<td>RCT, double-blind,</td>
<td>Prostate volume measured by</td>
<td>IM Testosterone Undecanoate vs placebo</td>
<td>No increase in TRUS volume with TRT No change in IPSS or PSA</td>
</tr>
<tr>
<td>et al, 2008</td>
<td></td>
<td></td>
<td></td>
<td>placebo-controlled</td>
<td>TRUS, PSA, IPSS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kalinchenko et al,</td>
<td>Russia, 2010</td>
<td>184</td>
<td>30 wk</td>
<td>RCT, double-blind,</td>
<td>IPSS</td>
<td>IM Testosterone Undecanoate vs placebo</td>
<td>No change in IPSS</td>
</tr>
<tr>
<td>et al, 42</td>
<td></td>
<td></td>
<td></td>
<td>placebo-controlled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haider et al, 2009</td>
<td>Multinational</td>
<td>122</td>
<td>24 mo</td>
<td>Prospectively</td>
<td>IPSS</td>
<td>IM Testosterone Undecanoate vs placebo</td>
<td>Decrease in IPSS with TU treatment (P&lt;.05)</td>
</tr>
<tr>
<td>Kenny et al, 2010</td>
<td>United States</td>
<td>27</td>
<td>3 mo</td>
<td>Prospectively</td>
<td>IPSS</td>
<td>Transdermal testosterone</td>
<td>No change in IPSS with TRT</td>
</tr>
<tr>
<td>Kenny et al, 2010</td>
<td></td>
<td></td>
<td></td>
<td>Open-label study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tan et al, 2013</td>
<td>Malaysia, 2013</td>
<td>114</td>
<td>48 wk</td>
<td>RCT, double-blind,</td>
<td>IPSS</td>
<td>IM Testosterone Undecanoate vs placebo</td>
<td>No Change in IPSS with TRT</td>
</tr>
<tr>
<td>Shigehara et al, 2011</td>
<td>Japan</td>
<td>46</td>
<td>12 mo</td>
<td>RCT with untreated</td>
<td>IPSS Qmax PVR Prostate volume</td>
<td>IM Testosterone Enthanate vs placebo</td>
<td>Decrease in IPSS &amp; Qmax with TRT (P&lt;.05)</td>
</tr>
<tr>
<td>Saad et al, 2007</td>
<td>Germany, 2007</td>
<td>28</td>
<td>12 mo</td>
<td>Prospective Uncontrolled</td>
<td>IPSS</td>
<td>IM Testosterone Undecanoate vs Transdermal</td>
<td>Both arms Demonstrated a decrease in IPSS compared to baseline (P = .05)</td>
</tr>
<tr>
<td>Yassin et al, 2014</td>
<td>Germany, 2014</td>
<td>152</td>
<td>5.5 y</td>
<td>Prospective Uncontrolled</td>
<td>IPSS</td>
<td>IM Testosterone Undecanoate</td>
<td>Decrease in IPSS from 10.35 to 6.31 with no statistical analysis</td>
</tr>
<tr>
<td>Karazindiyaoglu et al,</td>
<td>Turkey, 2008</td>
<td>25</td>
<td>12 mo</td>
<td>Prospective cohort study</td>
<td>IPSS, bladder compliance, maximal bladder capacity</td>
<td>Transdermal testosterone</td>
<td>Increase in bladder capacity and compliance with TRT (P&lt;.05).</td>
</tr>
</tbody>
</table>
Prostate Cancer and BPH

**AUA 2018 Guidelines**

Clinicians should inform patients of the absence of evidence linking testosterone therapy to the development of prostate cancer. *(Strong Recommendation; Evidence Level: Grade B)*

Patients with testosterone deficiency and a history of prostate cancer should be informed that there is inadequate evidence to quantify the risk-benefit ratio of testosterone therapy *(Expert Opinion)*

**Endocrine 2018 Guidelines**

We recommend against testosterone therapy in men with…. prostate cancer, a palpable prostate nodule or induration, a prostate-specific antigen level >4 ng/mL, a prostate-specific antigen level >3 ng/mL combined with a high risk of prostate cancer (without further urological evaluation)….severe lower urinary tract symptoms,… *(Low quality evidence)*
AUA Guidelines: Erectile Dysfunction
ERECTILE DYSFUNCTION: AUA GUIDELINE

Arthur L. Burnett, MD; Ajay Nehra, MD; Rodney H. Breau, MD; Daniel J. Culkin, MD; Martha M. Faraday, PhD; Lawrence S. Hakim, MD; Joel Heidelbaugh, MD; Mohit Khera, MD; Kevin T. McVary, MD; Martin M. Miner, MD; Christian J. Nelson, PhD; Hossein Sadeghi-Nejad, MD; Allen D. Seftel, MD; Alan W. Shindel, MD
Shared Decision-Making

- The Panel believes that *shared decision-making* is the cornerstone of the treatment and management of ED, a model that relies on the concepts of *autonomy and respect* for persons in the clinical encounter.

- All men should be *informed of all treatment options that are not medically contraindicated* to determine the appropriate treatment.

- Men may choose to begin with the least invasive option, the Panel notes that it is *valid for men to begin with any type of treatment*. 
Prior ED Treatment Paradigm

Male patient diagnosed with ED

1st line therapies

Oral ED therapies (PDE5i)

~75%

2nd line therapies

Urethral suppository

~5%

Injectable

<10%

Vacuum pump

<5%

3rd line therapies

Penile implant

~5%

Corrective vascular surgery

<1%

Prescribed by both Urologists & PCPs

Primarily prescribed by Urologists

Source: Adapted from American Urologic Association Treatment of ED Guidelines, emedicine.com, L.E.K. Consulting Interviews and analysis.
ERECTILE DYSFUNCTION ALGORITHM

COUNSEL THE MAN AND PARTNER REGARDING:
- The value of psychosocial/relationship support from trained professionals to optimize treatment satisfaction
- The importance of lifestyle change (weight loss, exercise, smoking cessation)
- To improve erectile function and overall health
- The benefits and risks/burdens of all available ED treatments that are not contraindicated

Using a shared decision-making framework, identify appropriate treatment based on values and priorities of man and partner

PDE5i, Vacuum devices, Intraurethral (IU) alprostadil, Intracavernosal injections (ICI), Penile prosthesis surgery

ASSESS OUTCOMES, ADVERSE EVENTS (AEs), AND SATISFACTION OF MAN AND PARTNER

IF INADEQUATE EFFICACY AND/OR UNACCEPTABLE AEs AND/OR INSUFFICIENT SATISFACTION, THEN ADDRESS AS APPROPRIATE:
- Dose adjustments (for PDE5i, IU alprostadil, ICI)
- Revisit instructions to maximize efficacy (for all treatments)
- Revisit values and priorities of man and partner with mental health professional to refine values and priorities and/or to address psychosocial or relationship barriers to successful treatment
- Consider alternate treatment

AUA ED Guidelines 2018
AUA ED Guideline Statements: Laboratory Testing

- Glucose/hemoglobin A1c, testosterone and serum lipids
- Serum total testosterone should be measured in all men with ED to determine if testosterone deficiency (TD), defined as total testosterone < 300 ng/dL with the presence of symptoms and signs.
AUA ED Guideline Statements: Treatment

• Men who desire preservation of erectile function after treatment for prostate cancer by radical prostatectomy (RP) or radiotherapy (RT) should be informed that early use of PDE5i post-treatment may not improve spontaneous, unassisted erectile function. (Moderate Recommendation; Evidence Level: Grade C)

• Men with ED and testosterone deficiency (TD) who are considering ED treatment with a PDE5i should be informed that PDE5i may be more effective if combined with testosterone therapy. (Moderate Recommendation; Evidence Level: Grade C)
AUA ED Guideline Statements: Treatment

- For men with ED who have decided on penile implantation surgery, counseling should be provided regarding post-operative expectations. (Clinical Principle)

- Penile prosthetic surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection. (Clinical Principle)

- For men with ED, penile venous surgery is not recommended. (Moderate Recommendation, Evidence Level: Grade C)
Shockwave Therapy to Treat ED

A Breakthrough Solution for Better Erections and Optimal Sexual Performance at Any Age
Different Forms of Shockwave Generators

- Radial pressure wave (RSWT)
- Electrohydraulic shockwave
- Electromagnetic shockwave
- Piezoelectric shockwave
- Pneumatic shockwave

Medispec  Dornier  Storz  Renova Direx  MTS Medical (TRT)  Haibin medical equipment

Courtesy of F. Giuliano
Cavernosal Tissue Response to Shockwaves

Activate nerve repair

Restore normal endothelial signaling

Recruit immune cells, initiate wound healing

Activate resident stem cells

Single-arm trials almost unanimously show beneficial effects in patients with vasculogenic ED, even in PDE5i non-responders.

RCTs have produced conflicting results, and have evaluated erectile function only a short time after treatment; several RCTs are highly biased.

Meta-analyses and systematic reviews conclude that shockwave therapy has an effect, but these analyses are limited by the fact that biased RCTs have been included in these analyses.

- No high-quality level 1a evidence is available and level 1b evidence is conflicting regarding the use of Li-ESWT for ED treatment.

CONCLUSION: Li-ESWT should be limited to clinical trials until large multi-centric RCTs have provided the necessary data to recommend the routine use of this promising novel technology as a first-line treatment.
AUA ED Guidelines: Low Intensity Show Wave Therapy

For men with ED, low-intensity extracorporeal shock wave therapy (ESWT) should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C)

Findings from randomized sham-controlled trials that have evaluated low-intensity ESWT do not clearly indicate that benefits reliably outweigh risks/burdens for men with ED. In particular, the treatment’s ability to restore normal erectile function remains in question, the duration of treatment effects beyond possible short-term efficacy is not well-established, and the burdens associated with obtaining the treatment (i.e., time and cost) are substantial. Given the availability of other treatments that are less burdensome and known to be effective and the fact that ESWT is not FDA-approved, the Panel concludes that ESWT should only be used in investigational settings in the context of an institutional review board (IRB)-approved clinical trial.
Emerging Tools for Erectile Dysfunction: A Role for Regenerative Medicine

The Current Status of Stem Cell Therapy in Erectile Dysfunction

Table 1. Summary of the 4 published clinical trials on stem-cell therapy for ED

<table>
<thead>
<tr>
<th>First author (year)</th>
<th>Number of men</th>
<th>Cause of ED</th>
<th>Treatment</th>
<th>Assessment</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bahk (2010) [53]</td>
<td>7</td>
<td>Diabetes</td>
<td>Umbilical blood SC</td>
<td>IIEF-5, SEP, GAQ</td>
<td>Improved rigidity in 2/7, able to penetrate with PDE5i</td>
</tr>
<tr>
<td>Levy (2016) [67]</td>
<td>8</td>
<td>Organic</td>
<td>Placental-derived SC</td>
<td>PSV, IIEF</td>
<td>3/8 improved erection; IIEF change not significant</td>
</tr>
<tr>
<td>Haahr (2016) [52]</td>
<td>17</td>
<td>5~18 months after radical prostatectomy</td>
<td>Adipose-derived SC</td>
<td>IIEF-5</td>
<td>8/11 continent men and 0/6 incontinent men recovered erection</td>
</tr>
<tr>
<td>You (2016) [51]</td>
<td>12</td>
<td>22 months after radical prostatectomy</td>
<td>Bone marrow mononuclear cells</td>
<td>IIEF-15, EHS, color Doppler ultrasound</td>
<td>1/12 hard erection; 9/12 needed ICI, PDE5i, or VCD. Improved EHS and IIEF</td>
</tr>
</tbody>
</table>

• Word of caution...
  • Only small number of clinical trials published in the literature
    • No control group
    • No randomization
  • Numerous clinics throughout the world are offering penile injections of “stem cells” for monetary gain to treat ED
  • Further larger randomized controlled trials are desperately needed in this field

F.D.A. Cracks Down on ‘Unscrupulous’ Stem Cell Clinics

By SHEILA KAPLAN and DENISE GRADY  AUG. 28, 2017
AUA ED Guidelines: Stem cells

For men with ED, intracavernosal stem cell therapy should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C)

Findings from studies that have evaluated ICI stem cell therapy do not indicate that benefits reliably outweigh risks/burdens for men with ED. In particular, the treatment’s ability to restore normal erectile function in various populations of men with ED has not been convincingly demonstrated. Further, neither the most effective source and dose of stem cells nor the duration of treatment effects has been established, and the burdens associated with obtaining the treatment (i.e., cost, need for tissue harvest) can be substantial. Given the paucity of data obtained in human participants, the risks of treatment also are not well-established.
Baylor College of Medicine
Stem Cell and ED Studies

**Human trials:**
- IRB and FDA approved clinic trial (NCT01601353)
- Randomized controlled trial
- Diabetic and radical prostatectomy patients
- Autologous adipose derived stem cells
- 30 patients completed study

**Animal experiments:**
- IRB approved experiments
- Diabetic rat model
- Autologous adipose derived stem cells
- Assessing optimal dosing and frequency of intracavernosal stem cell injections
Platelet Rich Plasma

1. Withdraw blood and place in tube
2. Centrifuge

- Plasma (55% of whole blood)
- Buffy coat: leukocytes and platelets (<1% of whole blood)
- Erythrocytes (45% of whole blood)
PRP Statistics

• No studies listed on www.clinicaltrials.gov for PRP and ED

• Google “Platelet rich plasma, erectile dysfunction”: 147,000 results (10/2017)

• Website marketing (2015) “bigger erections, improved sex life, improvement in climax/orgasm, increased sensation, increased libido” and “improved sensation even years after prostatectomy”

• Cost: $1500 to $3000 cash per injection

• 2018 first PRP/ED study published (case series)

Jenkins L et al. 2015 JSM 12(12) 2223-2225
Franco M, Garcia-Cruz E ESSM 2018
Safety and feasibility of platelet rich fibrin matrix injections for treatment of common urologic conditions

Ethan L Matz, Amy M Pearlman, Ryan P Terlecki
Department of Urology, Wake Forest Baptist Medical Center, Winston Salem, NC, USA

- 4 with ED only and 1 with ED and Peyronies disease
- Between 4 and 9 mL of PRP was injected in corpora cavernosa per treatment session. was
- A mean of 2.1 injection procedures per patient were performed
- IIEF-5 improvement of 4.14
- AEs (in all patients): mild pain (23.5%) and bruising (5.9%)
7. HOW CAN PLATELET RICH PLASMA (PRP) TREAT ERECTILE DYSFUNCTION?

The Priapus Shot, a revolutionary new procedure from the creators of the popular Vampire Facelift, can treat erectile dysfunction using platelet rich plasma (PRP). The Priapus Shot procedure is non-invasive and doesn't carry the heart-health risks that many traditional erectile dysfunction treatments do. The Priapus Shot uses natural, regenerative cells that are drawn from your bloodstream. These cells are refined to just the platelet rich plasma (PRP), using a highly-advanced centrifuge.

By administering platelet rich plasma directly to the penis, the Priapus Shot (also called the M-Shot) delivers erections that are:

- Firmer
- Larger
- More frequent
- Longer-lasting

Through PRP, the Priapus Shot promotes the growth of new tissue. The results of the Priapus Shot can help you have better erections for up to 18 months or longer. If you're interested in finally beating erectile dysfunction with the Priapus Shot, call ____________________________.

Click here for the erectile dysfunction intensity scale

The concept of penile rehabilitation was first studied by Montorsi et al. in 1997.

This recent study showed that using vasodilators combined with a penis pump improved erectile function post prostatectomy.

We're seeing an average improvement of 5-8 on an ED scale using a pump combined with PRP (the Priapus Shot® procedure).
AUA ED Guidelines: Platelet Rich Plasma

For men with ED, platelet-rich plasma (PRP) therapy should be considered experimental. (Expert Opinion)

PRP should not be offered to men with ED unless it is administered in the context of an IRB-approved experimental clinical research protocol. At this time, no full-text peer-reviewed publications are available to constitute an evidence base. Therefore, reliable information about potential benefits and risks/burdens of PRP therapy is not available. Because of the absence of evidence and given the availability of multiple other proven treatment options, it is the Panel’s expert opinion that PRP therapy is not appropriate for men with ED except as part of an IRB-approved research trial.
“Thus, given the current lack of regulatory agency approval for any restorative (regenerative) therapies for the treatment of ED and until such time as approval is granted, SMSNA believes that the use of shock waves or stem cells or platelet rich plasma is experimental and should be conducted under research protocols in compliance with Institutional Review Board approval. Patients considering such therapies should be fully informed and consented regarding the potential benefits and risks. Finally, the SMSNA advocates that patients involved in these clinical trials should not incur more than basic research costs for their participation.”
Testosterone Therapy Summary

• Clinicians prescribing testosterone therapy should be aware of the 2018 AUA and Endocrine Guidelines and the recent FDA label changes, including diagnosis, treatment, and indications for use

• Patients should be appropriately counseled on the risks of VTE, CVE, BPH and prostate cancer when prescribing testosterone therapy
Erectile Dysfunction Summary

- Patients should be informed of all treatment modalities that are not contraindicated, regardless of invasiveness or irreversibility, as potential first-line treatments and counseled the risks/benefits of each treatment.

- The use of shock waves, stem cells or platelet rich plasma is experimental and should be conducted under research protocols in compliance with Institutional Review Board approval.
Thank You

Texas Medical Center, Houston