Advances in the Treatment of Erectile Dysfunction

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2016 Las Vegas Hormone Replacement Therapy Symposium
Las Vegas, NV
February 11-13, 2016
Disclosure

Mohit Khera, M.D., M.B.A., M.P.H., is Associate Professor of Urology, Scott Department of Urology, Baylor College of Medicine. Conflict of interest was resolved through peer review of slide content.

Professional Education Services Group staff have no financial interest or relationships to disclose.

Disclosure

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Educational Grant Support

This continuing education activity is supported by an educational grant from PCCA.
Learning Objectives

• At the conclusion of this activity, the participant will be able to:
  • Explain how to diagnose Erectile Dysfunction.
  • Discuss all available treatment options for Erectile Dysfunction.
  • Discuss new paradigms in the treatment of Erectile Dysfunction.

Topics

• Erectile dysfunction through the ages
• Current ED treatment options
• Testosterone to treat ED
• Targeting the endothelium
• Treating the female partner
• Future potential ED therapies

Erectile Dysfunction Through the Ages

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Treating Erectile Dysfunction in Modern Times

Prevalence of ED: Massachusetts Male Aging Study

Men aged 40 to 70 years (N = 1290)

Massachusetts Male Aging Study (MMAS)

Overall prevalence of ED among men aged 40 to 70 years (N=1290) was 52%

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### Etiologies of ED\(^1-3\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasculogenic</td>
<td>Cardiovascular disease, hypertension, diabetes mellitus, hyperlipidemia, smoking, major surgery (radical prostatectomy) or radiotherapy (pelvis or retroperitoneum)</td>
</tr>
<tr>
<td>Neurogenic</td>
<td>Spinal cord and brain injuries, Parkinson’s disease, Alzheimer’s disease, multiple sclerosis, stroke</td>
</tr>
<tr>
<td>Local penile (cavernous) factors</td>
<td>Peyronie’s disease, cavernous fibrosis, penile fracture</td>
</tr>
<tr>
<td>Hormonal</td>
<td>Hypogonadism, hyperprolactinemia, hyper- and hypothyroidism, hyper- and hypocortisolism</td>
</tr>
<tr>
<td>Drug-induced</td>
<td>Antihypertensives, antidepressants, antipsychotics, antialdosterone, recreational drugs</td>
</tr>
<tr>
<td>Psychogenic</td>
<td>Performance-related issues, traumatic past experiences, relationship problems, anxiety, depression, stress</td>
</tr>
</tbody>
</table>


### Most Men With ED Do Not Receive Treatment

- In a study of 6,228,509 men with ED\(^1\)
  - 25.4% received treatment (ie, PDE5 inhibitor, injection or urethral prostaglandins or androgen replacement)
  - 74.6% were untreated
- In a population-based study of men 40 years and older with ED, 77% were not receiving pharmacotherapy with a PDE5 inhibitor\(^2\)
- Potential reasons for not seeking treatment\(^3\)
  - Feelings of shame
  - Concern that the physician won’t take the sexual problem seriously


### Diagnostic Evaluation of Men with ED

1. Patient with ED (self-reported)
2. Medical and psychosexual history (use of validated instruments, eg, IIEF)
3. Identify other sexual problems
4. Identify common causes of ED
5. Identify reversible risk factors for ED
6. Assess psychosocial status
7. Laboratory tests
   - Glucose-lipid profile (if not assessed in the last 12 months)
   - Total testosterone (morning sample)
   - If indicated, bioavailable or free testosterone
8. Focused physical examination
   - Penile deformities
   - Prostatic disease
   - Signs of hypogonadism
   - Cardiovascular & neurological status

Adapted from Wespes E, et al. European Association of Urology Guidelines on Male Sexual Dysfunction
Treatment Algorithm for ED

Identify and treat "curable" causes of ED
- Lifestyle changes and risk factor modification

Provide education and counseling to patients and partners

Treatment of ED

Identify patient needs and expectations
- Shared decision making

Offer conjoint psychosocial and medical treatment

PDE5 inhibitors
- Assess responsiveness
- Adverse effects
- Treatment satisfaction

Intracavernous injections
- Intracavernous injection technique
- Patient counseling and counseling and education
- Generate interest in combination therapy
- Consider patient satisfaction

Vacuum devices
- Consider patient satisfaction

Intraurethral alprostadil
- Consider patient satisfaction

Assess therapeutic outcome:
- Erectile response
- Side effects
- Treatment satisfaction

Consider penile prosthesis implantation

Inadequate treatment outcome
- Assess adequate use of treatment options
- Provide new instructions and counseling
- Retrial
- Consider alternatives or combination therapy

Current ED Treatment Approaches

Male patient diagnosed with ED

Oral ED therapies (Viagra, Cialis, Levitra, Staxyn)
- 1st line therapies

Intracavernous injections (EDEX, Caverject, mixes)
- 2nd line therapies

Intraurethral alprostadil
- 3rd line therapies

Penile implant

Vacuum pump

Prescribed by both Urologists & PCPs

Primarily prescribed by Urologists

PDE5 Inhibitors: Pharmacokinetics

<table>
<thead>
<tr>
<th></th>
<th>Sildenafil1</th>
<th>Tadalafil2</th>
<th>Vardenafil3</th>
</tr>
</thead>
<tbody>
<tr>
<td>T_max (min)</td>
<td>60</td>
<td>120</td>
<td>60</td>
</tr>
<tr>
<td>Terminal t1/2 (hrs)</td>
<td>4</td>
<td>17.5</td>
<td>4-5</td>
</tr>
<tr>
<td>Impact of a high fat meal</td>
<td>Mean delay in T_max of 60 minutes; mean reduction in C_max of 25%</td>
<td>Rate and extent of absorption are not influenced by food</td>
<td>Reduction in C_max of 18-50%</td>
</tr>
<tr>
<td>Recommended administration times</td>
<td>~60 minutes before sexual activity</td>
<td>~60 minutes before sexual activity</td>
<td>Use as needed prior to sexual activity</td>
</tr>
</tbody>
</table>


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**Avanafil**

- **T_{max} (min):** 30-45 min
- **Terminal t_{1/2} (hrs):** 5 hours
- **Impact of a high fat meal:**
  - Rate of absorption is reduced, T_{max} of 1.12 to 1.25 hours and a mean reduction in C_{max} of 39% (200 mg)
  - 3.8% decrease in AUC
- **Recommended administration times:** 30 minutes prior to intercourse

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**IMPORTANT SAFETY INFORMATION**

- Administration of PDE5is with any form of organic nitrates, either regularly and/or intermittently, is contraindicated. PDE5is have been shown to potentiate the hypotensive effects of nitrates
- Patients with the following characteristics (recent serious cardiovascular events, resting hypotension or uncontrolled hypertension, unstable angina, angina with sexual intercourse, New York Heart Association Class 2 or greater congestive heart failure, or hereditary degenerative retinal disorders, including retinitis pigmentosa) were not included in the clinical safety and efficacy trials. PDE5is are therefore not recommended for those patients
- Caution is advised when PDE5 inhibitors are coadministered with alpha-blockers. Patients who demonstrate hemodynamic instability on alpha-blocker therapy alone are at increased risk of symptomatic hypotension with concomitant use of PDE5 inhibitors. Patients should be stable on alpha-blocker therapy prior to initiating treatment with a PDE5 inhibitor. In those patients who are stable on alpha-blocker therapy, PDE5 inhibitors should be initiated at the lowest dose

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**PDE5i Market Share Trends**

<table>
<thead>
<tr>
<th></th>
<th>Jan-08</th>
<th>Jun-08</th>
<th>Nov-08</th>
<th>Apr-09</th>
<th>Sep-09</th>
<th>Feb-10</th>
<th>Jul-10</th>
<th>Dec-10</th>
<th>May-11</th>
<th>Oct-11</th>
<th>Mar-12</th>
<th>Aug-12</th>
<th>Jan-13</th>
<th>Jun-13</th>
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<tr>
<td>Cialis</td>
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<td>220,000</td>
<td>230,000</td>
<td>240,000</td>
<td>250,000</td>
<td>260,000</td>
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<td>310,000</td>
<td>320,000</td>
<td>330,000</td>
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<tr>
<td>Levitra</td>
<td>200,000</td>
<td>180,000</td>
<td>160,000</td>
<td>140,000</td>
<td>120,000</td>
<td>100,000</td>
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<td>20,000</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>Staxyn</td>
<td>200,000</td>
<td>170,000</td>
<td>140,000</td>
<td>110,000</td>
<td>80,000</td>
<td>50,000</td>
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<tr>
<td>Viagra</td>
<td>200,000</td>
<td>180,000</td>
<td>160,000</td>
<td>140,000</td>
<td>120,000</td>
<td>100,000</td>
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<td>40,000</td>
<td>20,000</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

- PDE5i market stable (1.4%) CAGR
- Cialis outpacing competition in growth (5.7%) CAGR
- Viagra and Staxyn minimal increase in share over last year
- Levitra continues volume and share decline following Staxyn launch

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Testosterone to Treat ED

Erectile Dysfunction and Testosterone

- Androgen deprivation is thought to negatively impact erectile function through four major mechanisms:
  - Impairment of nitric oxide synthase release
  - Altered phosphodiesterase type 5 expression and activity
  - Impaired cavernosal nerve function
  - Contribution to veno-occlusive disease
- Testosterone supplementation significantly improves erectile function in men with ED

Androgens Enhance PDE5i Efficacy

- **Shabsigh et al.¹**
  - 75 hypogonadal men (T<400 ng/dl) failed sildenafil 100mg
  - Randomize to testosterone gel or placebo
  - All men received sildenafil 100 mg as needed for 12 weeks
  - IIEF significantly improved in TRT vs placebo (4.4 vs 2.1, p=0.029)
- **Rosenthal et al.²**
  - 24 hypogonadal men failed 3 trials of sildenafil 100mg within 3 months
  - Started on 4 weeks of testosterone gel and then restarted on sildenafil
  - After 16 weeks, 92% of men who initially failed sildenafil therapy reported improvements in potency
- **Khera et al.³**
  - Multicenter registry of hypogonadal men (n=849) treated with TRT and followed for 12 months
  - Patients already on PDE5i therapy also had a significant increase in BMSFI scores after starting TRT

References:

² Rosenthal et al. Urology 2006 Mar; 67(3):571-4
³ Khera et al. JSM 2011 Nov;8(11):3204-13

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Intracavernosal Injection Therapy (ICI)

- Caverject
- EDEX (Alprostadil)
- Trimix (PGE, Phentolamine, Papaverine)

Lyophilized Compounded Trimix

- Each vial is diluted with 0.5cc of NS prior to use
- No need for refrigeration

MUSE Intraurethral Suppository
The Endothelium: A New Target for the Treatment of Erectile Dysfunction

Correlation Between ED and CVD

- Thompson et al. 2005¹
  - 4,247 men without ED
  - 57% with ED at 5 years
  - Men with ED had a significantly higher incidence of developing CVD

- Montorsi et al. 2005²
  - Prevalence of ED was 49% in men with symptomatic CAD.
  - Patients noticed ED on average 39 months before the onset of angina.

¹ Thompson et al JAMA 2005; 294:2996
² Montorsi et al Eur Urol 2003; 44:360
³ Montorsi et al AJC 2005; 96(12): 19M

Common Link Between ED and Cardiovascular Disease: Endothelial Injury

How Can We Assess the Endothelium?

- Serum Markers
  - Endothelin (ET-1)
  - Interleukin-6 (IL-6)
  - Tumor necrosis factor (TNF)
  - C-reactive protein (CRP)
- Cellular Markers
  - Endothelial progenitor cells (cEPCs)
- Imaging
  - Physiological measurement
    - Flow-mediated dilation of the brachial artery
    - Peripheral arterial tonometry (PAT)

Peripheral Arterial Tonometry (PAT) Using EndoPat 2000

- FDA approved
- Blood-pressure cuff inflated to suprasystolic pressures for 5 minutes and then released to induce reactive hyperemia
- Finger probes assess changes in volume associated with pulse waves
- Data automatically analyzed and reactive hyperemic index (RHI) computed.

Common Link Between ED and Cardiovascular Disease: Endothelial Injury

Targeting the Endothelium to Treat CAD

- Improve in Insulin Resistance
- Aspirin
- Smoking Cessation
- Statin
- Improvement in Endothelial Function
- Chronic PDE5i
- Diet and Exercise
- Improvement in Cardiac Blood Flow
- Treatment of CAD

Targeting the Endothelium to Treat ED

- Improve in Insulin Resistance
- Aspirin
- Smoking Cessation
- Statin
- Improvement in Endothelial Function
- Chronic PDE5i
- Diet and Exercise
- Improvement in Penile Blood Flow
- Treatment of ED

Diet and Exercise to Treat ED

- Randomized, single-blinded trial of 110 obese men without other co-morbidities and an IIEF score 21 or less
- 55 men seen by nutritionist and exercise counselor to lose 10% or more of total body weight (intervention group)
- 55 men with no counseling (control group)
Diet and Exercise to Treat ED

- **Results (after 2 years)**
  - Intervention group had a significant reduction in BMI (36.9 to 31.2) compared to control group (36.4 to 35.7)
  - Intervention group had a significant reduction in IL-6 and c-reactive protein
  - **IIEF-5 scores**
    - Intervention group: 13.9 to 17 (p<0.05)
    - Control group: 13.5 to 13.6
  - In multivariate analyses, changes in body mass index ($P = .02$), physical activity ($P = .02$), and C-reactive protein ($P = .03$) were independently associated with changes in IIEF score.

Targeting the Endothelium to Treat ED

- **Improvement in Penile Blood Flow**
  - **Improvement in Endothelial Function**
  - **Aspirin**
  - **Smoking Cessation**
  - **Chronic PDE5i**
  - **Testosterone Replacement**

Statins to Improve ED

- 18 men with hyperlipidemia as only risk factor for ED
- Organic ED verified by abnormal nocturnal penile tumescence testing and with SHIM questionnaire
- Patients given Atorvastatin with goal to decrease cholesterol to <200 mg/dl.
- **Results (after 4 months)**
  - 88% of men had improved erection adequate for penetration
  - Mean SHIM scores improved from 14.2 to 20.7 (p<0.001)
  - Significant improvement in mean RigiScan scores.

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Saltzman et al. J Urol 2004; 172:255v

Esposito et al. JAMA. 2004;291:2978-2984

Saltzman et al. J Urol 2004; 172:255v

Herrmann. JSM 2006

Saltzman et al. J Urol 2004; 172:255v

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Statins to Improve ED

• R, DB, PCT
• 12 Men with moderate to severe ED (IIEF <16) despite adequate sildenafil trial
• Improvement in sildenafil response reassessed at 6 and 12 weeks after daily treatment with atorvastatin 80mg vs placebo

Hermann et al JSM 2006;3:303

Statins to Improve ED

• Results
• Treatment with atorvastatin decreased mean low-density lipoprotein cholesterol by 43%
• By 6 weeks, the mean IIEF domain score increased from 10.3 to 18.0 with use of sildenafil in atorvastatin-treated patients (p<0.5)
• The increase in IIEF score in placebo patients was not statistically significant.

Hermann et al JSM 2006;3:303

The Effect of Statins on Erectile Dysfunction: A Meta-Analysis of Randomized Trials

John B. Koets, MD and Jarew M. Dobrzynski, BA
Cardiovascular Institute, Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ, USA

• Meta-analysis of 11 randomized trials assessing the effects of statins on erectile function
• IIEF increased by 3.4 points (95% CI 1.7–5.0, P = 0.0001) with statins compared to control
• Increase in IIEF with statins was approximately one-third to one-half of phosphodiesterase-5 inhibitors and larger than the effect of lifestyle modification
• Average age of participants and the degree of LDL cholesterol lowering did not alter the effect on IIEF

Koets et al JSM 2014
Targeting the Endothelium to Treat ED

- Improvement in Insulin Resistance
- Aspirin
- Smoking Cessation
- Statin
- Diet and Exercise
- Improvement in Penile Blood Flow
- Improvement in Endothelial Function
- Testosterone Replacement
- Chronic PDE5i
- Treatment of ED

Chronic PDE5i to treat ED

- Randomized controlled trial with 20 men with ED treated with tadalafil 20mg on alternate days (chronic treatment) or on demand (OD) for 4 weeks
- Primary endpoints
  - Peak systolic velocity (PSV)
  - Flow-mediated dilation of cavernous arteries
- Secondary endpoints
  - Q13-SIED scores regarding morning erections
  - Markers of endothelial dysfunction: VCAM, ET-1, CRP

Aversa et al. IJIR 2007; 19:200

Chronic PDE5i to Treat ED

- Results
  - PSV and FMD were higher after chronic treatment compared with OD treatment
  - Chronically treated patients had greater improvement in morning erections compared to OD patients
  - ET-1, VCAM, CRP were significantly reduced in chronically treated patients (not in OD patients) and this effect was sustained up to 3 months after cessation of treatment

Aversa et al. IJIR 2007; 19:200
Targeting the Endothelium to Treat ED

- Improvement in Insulin Resistance
- Aspirin
- Smoking Cessation
- Statins
- Improvement in Endothelial Function
- Diet and Exercise
- Testosterone Replacement
- Improvement in Penile Blood Flow
- Treatment of ED

Effects of Testosterone Undecanoate on Cardiovascular Risk Factors and Atherosclerosis in Middle-Aged Men With Late-Onset Hypogonadism and Metabolic Syndrome: Results From a 24-month, Randomized, Double-Blind, Placebo-Controlled Study

- N=50 men, between 45 and 65 years
- N=25 men on T Therapy and 25 men on placebo
- Mean age, 57-58 years
- Hypogonadism: TT <300 ng/dL (<11 nmol/L), or cFT <10 pg/mL (<250 pmol/L)

- Results were so positive at 12 months that the placebo patients were started on T Therapy as well


CIMT After 12 Months of long-acting testosterone undecanoate injection Treatment (n=40) and Correlation Between Change in Testosterone and CIMT

- CIMT=carotid intima-media thickness

Baylor Protocol: Endothelial Evaluation and Treatment for Men Presenting with ED

- BMI
- 5 questionnaires
- Laboratory testing:
  - C-reactive protein
  - Testosterone, Free testosterone, estradiol
  - Hg A1c
  - Apo B
  - Urine microalbumin
- Specialized testing:
  - EndoPat 2000
  - Penile duplex
  - Biothesiometry
- If RHI scores ≤1.8:
  - Lifestyle modifications: diet and exercise program (include nutritionist referral), smoking cessation (Chantix)
  - Daily PDE5i
  - Daily statin
- If also ≥2 cardiac risk factors, referral for cardiac evaluation if not previously done
- Hypogonadal patients treated with testosterone

Treatment of Female Sexual Dysfunction for the Treatment of ED

Sexual Dysfunction: A Couple’s Disease
Prevalence of FSD in Men with ED

- Female Experience of Men’s Attitudes to Life Events and Sexuality (FEMALES)
- 293 female partners of men with ED
- 43% of women reported having female sexual dysfunction
- Only 9% reported seeking treatment

Prevalence of ED in Women with FSD

- Questionnaires sent to 580 women with FSD
- 133 responses returned
- Results
  - Premature ejaculation: 20.2%
  - Erectile Dysfunction: 28.7%

FSD Improves When Partners are Treated with Vardenafil for ED

- Randomized, double-blinded, placebo-controlled trial
- 229 men with ED were treated with vardenafil vs placebo
- All men and their female partners received questionnaires before and after treatment
- Men: treated with vardenafil had a significant improvement in ED
- Women: significant improvement in sexual desire, arousal, lubrication, orgasm, and overall satisfaction
- Greater improvements in ED scores correlated with a greater improvements in FSD scores
Treatment of Erectile Dysfunction

Lifestyle Modifications

- Lubrications
- Weight loss
- Sex therapy
- Biofeedback
- Pelvic floor exercises
- Vaginal dilators
- Relaxation techniques
  - Massage therapy
  - Yoga
- Smoking cessation
- Stop or change medications
- Treat male ED
Medical Therapy for Female Sexual Dysfunction

- Hormonal Therapy
  - Estrogen
    - Local or systemic
  - Progesterone
  - DHEA-S
  - Testosterone

- Non-hormonal Therapy
  - Sildenafil Citrate / PDE5i
  - Bupropion
  - Cabergoline and other dopamine
  - Natural supplements

Addyi: “Female Viagra”

NITRIC OXIDE-RELEASING POLYMERS AS THERAPY FOR ERECTILE DYSFUNCTION
GOAL

• Urologist injects a long-acting medication every 4-6 months in the patient’s corpora cavernosa and eliminates the need for on demand or daily erectogenic medications.

MICROSPHERE FABRICATION

Photoinitiated Crosslinking


PEG-Lys₄-NO/PEGDA MICROSPHERES

100 µm
**Fluorescence Imaging**

PEG microspheres tagged with Alexa Fluor 750 fluorescent dye and injected intracavernosally through small perineal incision in 5 rats to ensure no local or distant migration of microspheres.

Day 0

Day 14

---

**In vivo Study Design**

Diabetes chemically induced using Streptozocin \((n=32)\)

12 week old male Sprague-Dawley Rats \((n=40)\)

ARM 1

Age-matched Controls \((n=8)\)

Diabetes chemically induced using Streptozocin \((n=32)\)

Glucose check at 3 days, 4 weeks, & 8 weeks to ensure >250 mg/dl

ARM 2

Diabetic \((n=7)\)

ARM 3

Diabetic + IV Sildenafil \((n=5)\)

ARM 4

Diabetic + NO-microspheres \((n=5)\)

ARM 5

Diabetic + NO-microspheres + IV Sildenafil \((n=5)\)

Death or Euthanasia \((n=8)\)

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**Experimental Setup**
ICP/MAP Ratio

**n = 5-8**

- Control
- Diabetic
- Diabetic + Sildenafil
- Diabetic + NO-microspheres
- Diabetic + NO-microspheres + Sildenafil

* *p* < 0.05 response significantly different compared to diabetic arm
** **p* < 0.05 response significantly different compared to sildenafil and diabetic arm

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Mesenchymal Stem Cell Therapy for the Treatment of Erectile Dysfunction

Mohit Khanna, MD, MBA, MPH,1 Maarit Albersen, MD, PhD,2 and John P. Mulhall, MD2

1Department of Urology, Reinaert College of Medicine, Houston, TX, USA; 2Department of Urology, University of Illinois at Chicago, Chicago, Ill. (Department of Urology, Memorial Sloan-Kettering Cancer Center, New York, NY, 10065)

- The first stem cell study for the treatment of ED was published in 2004
- The only study to use embryonic stem cells to treat ED
- Today a total of 36 published basic studies assessing stem cell therapy for ED, with only two being a small clinical trial
- Mechanism: Angiogenesis and increase in cavernosal smooth muscle

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Penile Low-Intensity Shock Wave Therapy: A Promising Novel Modality for Erectile Dysfunction

Tamer El-Erian, Asa-Elheim,1,2,3 Noam D. Krieger,1,2,3,4 Eitan Grossmold,1,2,3,4 Rosa Appel,1,2,3,4 Yoram Vardi1

Department of Urology, Reinaert College of Medicine, Houston, TX, USA; 1Department of Urology, Memorial Sloan-Kettering Cancer Center, New York, NY, 10065; 2Department of Urology, Memorial Sloan-Kettering Cancer Center, New York, NY, 10065; 3Memorial Sloan-Kettering Cancer Center, New York, NY, 10065; 4Department of Urology, Memorial Sloan-Kettering Cancer Center, New York, NY, 10065

- 1500 shocks 2 x per week for 3-6 weeks
- Angiogenic properties and stimulates neovascularization
- Improve penile blood flow and endothelial function
- Convert PDE5i non-responders to responders
- After 2 years, about half of the patients maintain their improvement in erectile function

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Conclusion
- Testosterone therapy should be considered as a treatment option in hypogonadal men with ED.
- The endothelium offers a new and exciting target for the treatment of erectile dysfunction.
- The treatment of ED should take into account the status and potentially treatment of the female partner sexual function.
- NO cavernosal microspheres, stem cells and LIST may offer new future treatment options for ED.

Thank you for your attention

Case #1
- Bill is a 59 y/o male with a 2 year history of worsening ED. He is unable to maintain his erections. He is happily married but ED causing stress in marriage.
- PMH: HTN, gout
- PSx: hernia, TURP
- Social: smokes 2ppd, occ ETOH
- PE: testis- 18cc bilaterally, DRE- 50 grams and benign, B DP pulses 1+
- Labs: PSA 2.5
- Next step?
Thank you

Questions?

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