

PHYSICIAN HEALTH TALK:

ED Treatment Options Beyond
PDE-5 Inhibitors

Physician Presenter Disclaimer



Products discussed in this presentation may be subject to regulatory approval / clearance and therefore labeling may change. Opinions given during this presentation are my personal, professional opinion.

This lecture and demonstration is intended as a supplement to your own education and training and is not a substitute for your own medical judgment.

(Note to physician: Review disclaimer and insert appropriate language and/or content changes to fit your individual circumstances)

Why Are We Here?



- Goals
- Understand your role of the health care provider in the treatment of Erectile Dysfunction (ED)
 - Understand ED treatment options beyond PDE-5 inhibitors
 - Understand the subspecialty of Prosthetic Urology

Erectile Dysfunction (ED)



What is it?

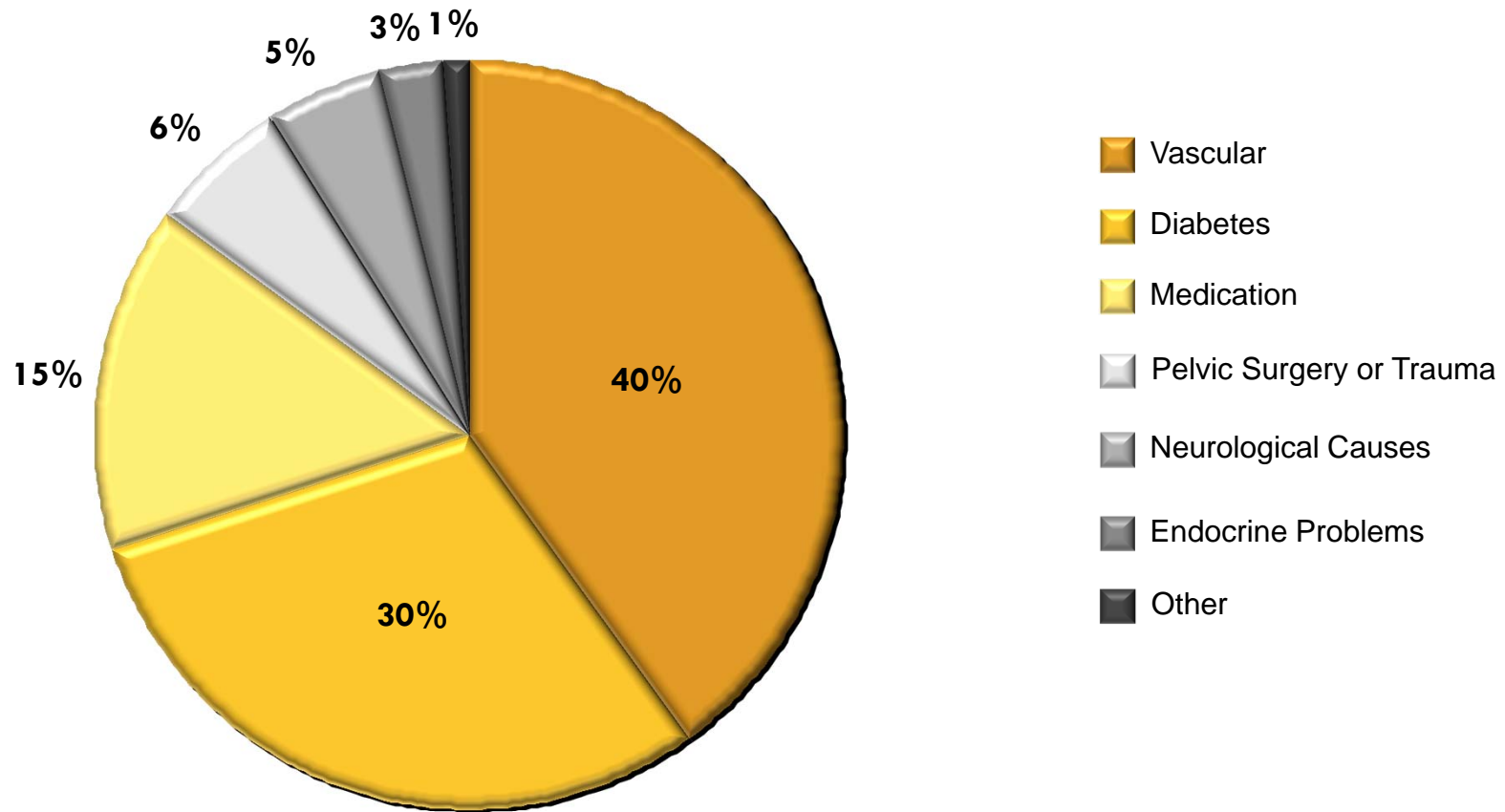
- The inability to maintain an erection firm enough to have sexual intercourse

How prevalent is it?

- ~1 in 5 American men ≥ 20 years old¹
- Over 30 million American men²

1. Selvin E, Burnett A, Platz E. Prevalence and risk factors for erectile dysfunction in the U.S. Am Jour of Med 2007 (120) 151-157.
2. National Institutes of Health (NIH) website. <http://kidney.niddk.nih.gov/kudiseases/pubs/ED/index.aspx>. Downloaded 5/14/12.

Main Physical Causes of ED³

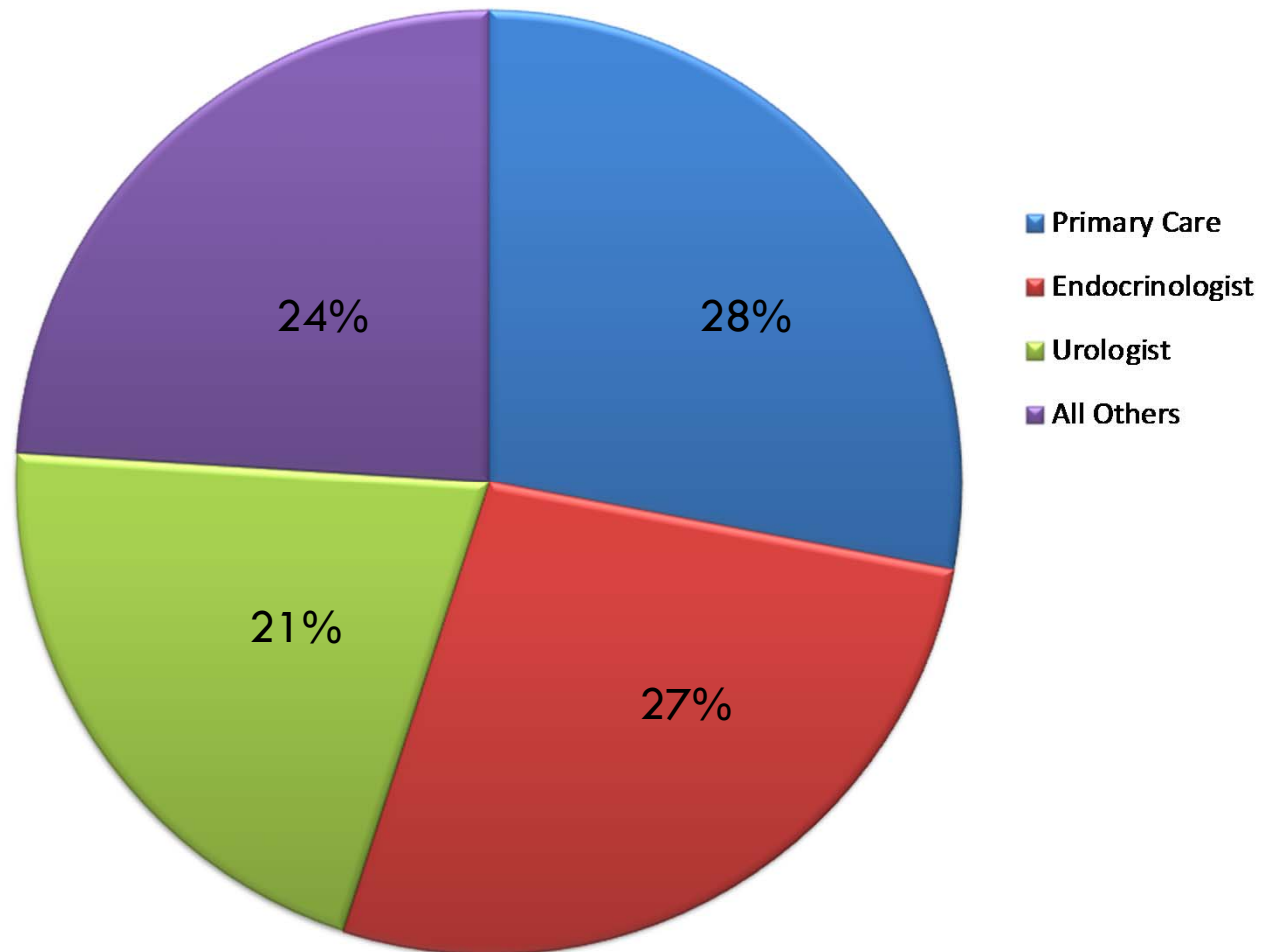




ED:

How Men Are Being Treated

Who Prescribes ED Medications?⁴



4. Brunk D. Erectile Dysfunction: 75% With Diagnosis Go Untreated <http://www.practiceupdate.com/news/2452> 2013

When PDE-5 Inhibitors Don't Work...

Patients who have failed a trial with phosphodiesterase type 5 (PDE5) inhibitor therapy should be informed of the benefits and risks of other therapies, including the use of⁵:

- A different PDE5 inhibitor
- Alprostadil intraurethral suppositories
- Intracavernous drug injection
- Vacuum erection devices
- Penile implants

Refer patient to an ED Specialist so that additional therapies can be offered.⁶

5. American Urological Association Education and Research, Inc. The Management of Erectile Dysfunction: An Update. *Guideline on the Management of Erectile Dysfunction: Diagnosis and Treatment Recommendations*, 2005; 1:14.

6. Miner M.M., Kuritzky L. Erectile Dysfunction: A sentinel marker for cardiovascular disease in primary care. *Cleveland Clinic Journal of Medicine*. 2007 May; 74 (3); 30-37.

Vacuum Erection Device⁷

- Externally applied device mechanically effects penile blood engorgement
- Cylinder/pump placed over penis creates closed chamber; pump slowly creates vacuum, drawing blood into corpora cavernosa
- Constrictive elastic ring then placed (max 30 minutes) at base of penis to restrict blood flow out of penis

Product Characteristics⁸

- Non-invasive
- Drug free

Adverse Events

- Bruising/burst blood vessels⁹
- Penile pain/discomfort⁹
- Penile Numbness⁹
- Delayed ejaculation⁹
- Erection is not warm to the touch; different color⁶



6. Miner M.M., Kuritzky L. Erectile Dysfunction: A sentinel marker for cardiovascular disease in primary care. Cleveland Clinic Journal of Medicine. 2007 May; 74 (3); 30-37.

7. Levine L, Dimitriou R. Vacuum constriction and external erection devices in erectile dysfunction. Urologic Clinics of North America 2001 May (28) No. 2, 335-341.

8. Yuan J., et al. Vacuum therapy in erectile dysfunction – science and clinical evidence. International Journal of Impotence Research. 2010; 12: 211-219.

9. The Process of Care Consensus Panel. The process of care model for evaluation and treatment of erectile dysfunction. Int J Impot Res. 1999;11:59-70. Position Paper.

Intraurethral Alprostadil (MUSE™†)¹⁰

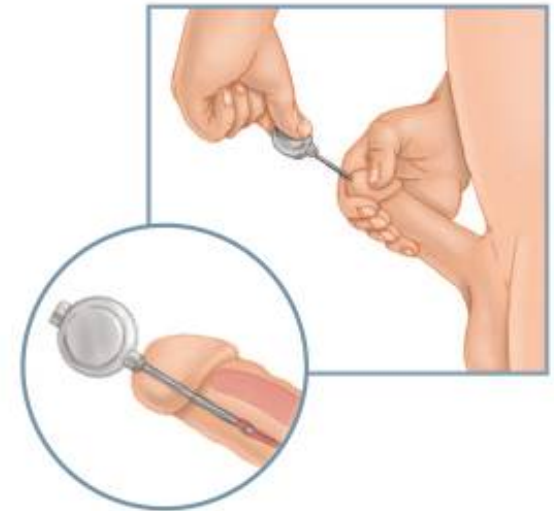
- Alprostadil chemically identical to prostaglandin E₁
 - Vasodilatory effects increase blood flow to penis

Product Characteristics

- No needles or injections
- Erection within 5 to 10 minutes
- Must be refrigerated

Adverse Events

- Pain (penis, urethra or testes)
- Urethral bleeding/spotting
- Hypotension
- Dizziness



Intracavernous Injection Therapy^{1 1}

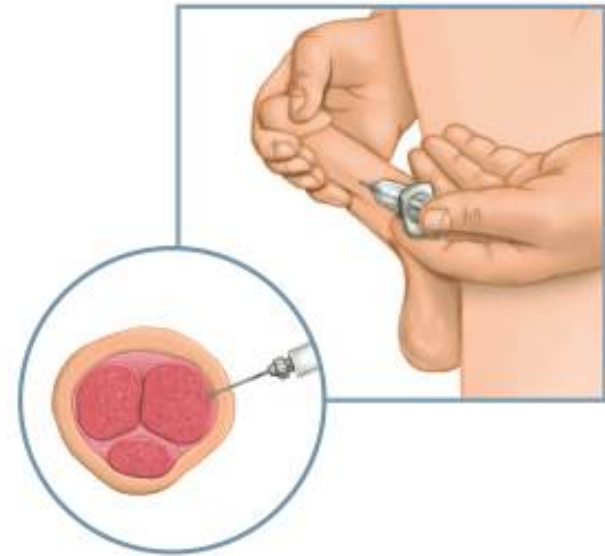
- Injected directly into corpora cavernosa

Product Characteristics

- On-set of erection within 5 to 20 minutes

Adverse Events

- Penile pain
- Prolonged erection
- Penile fibrosis
- Injection site hematoma



Penile Implants

- On the market for over 40 years and over 300,000 implants have returned to a satisfying sex life¹⁴
- High patient and partner satisfaction rates reported in clinical studies^{12,13}
- May offer a longer term treatment option to ED¹⁶
- 3-piece, 2-piece, and 1-piece (malleable) options available

Product Characteristics

- Totally contained in the body¹⁵
- Typically does not interfere with ejaculation or orgasm¹⁶
- Designed to be like a natural erection¹⁵
- Expands in girth and length¹⁵
- Once activated, the patient can maintain an erection suitable for intercourse¹⁵



Adverse Events

- Will make latent natural or spontaneous erections as well as other interventional treatments impossible
- If an infection occurs, the implant may have to be removed
- May cause the penis to become shorter, curved or scarred
- There may be mechanical failures of the implant
- Urogenital pain (typically associated with healing process)

12. Levine LA, Estrada CR, Morgentaler A. Mechanical reliability and safety of, and patient satisfaction with the Ambicor inflatable penile prosthesis: results of a 2 center study. J Urol. 2001 Sep;166(3): 932-7.

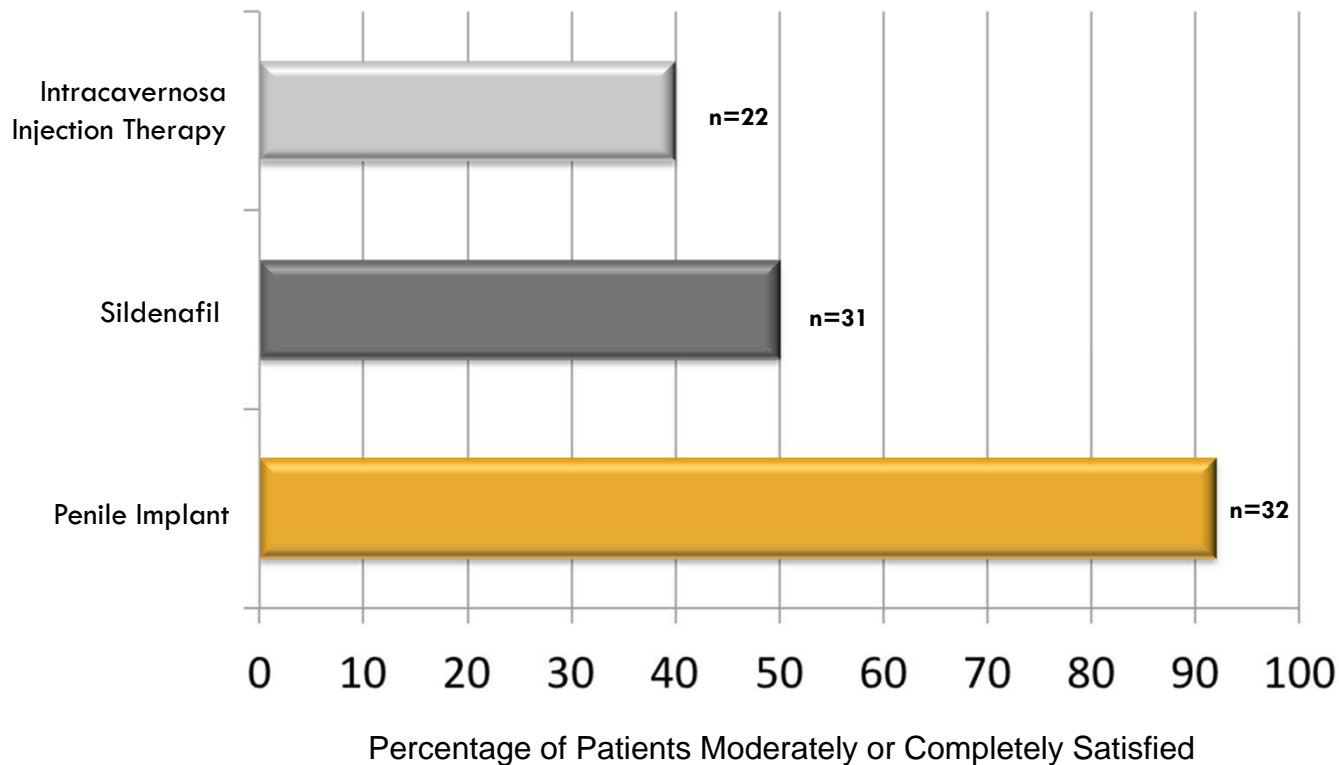
13. Montorsi F, et al. AMS Three-piece inflatable implants for erectile dysfunction: a long-term multi-institution study in 200 consecutive patients; Eur Urol. 2000; 37: 50-55.

14. European Society for Sexual Medicine (ESSM) Website, downloaded 1/8/09

15. AMS 700™ Patient Manual. Information and Instructions for Patients Considering an Inflatable Penile Prosthesis. American Medical Systems, Inc. 2012.

16. AMS 700™ Penile Prosthesis Product Line Instructions for Use. American Medical Systems, Inc. 2012.

Patient Satisfaction with ED Treatments in One Clinical Study¹⁷



Rates of overall satisfaction using Erectile Dysfunction Inventory for Treatment Satisfaction (EDITS) questionnaire were recorded in men treated consecutively at a single urology practice following therapy with 3 forms of ED treatment. Results were not statistically compared.

17. Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. J Urol Jul 2003 v.170 (1) p.159-63.

Why is it important to understand the subspecialty of prosthetic urology?

- Not every urologist is a prosthetic urologist
- A prosthetic urologist can offer the complete spectrum of treatment options
- Not all urologists perform the penile implant procedure; prosthetic urologists have training and experience in implant procedures
- Finding satisfying treatment options to erectile dysfunction can be a life-changing event for many men and their partners

QUESTIONS?

©2014 American Medical Systems, Inc. ("AMS"). The grant of permission to use AMS's copyrighted material does not constitute endorsement by AMS of any persons, products, services, or organizations.

ED-00951(1)/April 2014