Physician Health Talk: Treatment Options Beyond PDE-5 Inhibitors
This Presentation

• Has been developed in conjunction with American Medical Systems

• Is intended as a supplement to your own education and training and is not a substitute for your own medical judgment
Why Are We Here?

Goals

• Understand the role of the Primary Care Physician in the treatment of Erectile Dysfunction

• Understand Erectile Dysfunction 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 old\(^1\)
- Over 30 million American men\(^2\)

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Main Physical Causes of ED

- Vascular: 40%
- Diabetes: 30%
- Medication: 15%
- Pelvic Surgery, Radiation or Trauma: 6%
- Neurological Causes: 5%
- Endocrine Problems: 3%
- Other: 1%

ED:
In the Primary Care Setting
PCPs Prescribe the Majority of ED Medications

**ED Market Writers by Specialty**

- **PCP (Family/General Practitioner & Internal Medicine)**: 44.1%
- **NP/PA**: 13.8%
- **Urologist**: 39.3%
- **All Others**: 2.8%

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4. IMS Xponent, 12 months ending July 2011. (July ’10 – July ’11)
Treatment Options
Your Patient’s PDE-5 inhibitor isn’t working…What Now?

After re-education and counseling, which includes information on patient and partner expectations, proper drug administration, and titration to maximum dosing, evidence has shown that sildenafil therapy becomes successful in some men who were not previous responders.5

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 constriction devices
- Penile prostheses

Refer patient to a ED Specialist so that additional therapies can be tried by the patient6

Vacuum Constriction Device

- 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

Vacuum Constriction Device

Product Characteristics

- Non-invasive
- Drug free
- Cost effective

Adverse Events

- Erection is not warm to the touch; different color
- Bruising/burst blood vessels
- Penile pain/discomfort
- Penile Numbness
- Delayed ejaculation

Intraurethral Alprostadil (MUSE®)

- Alprostadil suppository (MUSE®*)
- Alprostadil chemically identical to prostaglandin E$_1^{11}$
  - Vasodilatory effects increase blood flow to penis$^{11}$

Product Characteristics$^{11}$

- No needles or injections
- Erection within 10 to 15 minutes
- Must be refrigerated

Intraurethral Alprostadil (MUSE®)

Adverse Events

• Pain – penis, urethra or testes
• Urethral bleeding/spotting
• Hypotension
• Dizziness

Intracavernous Injection Therapy

- Alprostadil (Caverject®) most widely used agent\textsuperscript{12}
- Injected directly into corpora cavernosa\textsuperscript{13}

Product Characteristics

- On-set of erection within 5 to 20 minutes\textsuperscript{13}

\textsuperscript{13} Caverject® PI, Revised 08/2009.
Intracavernous Injection Therapy

Adverse Events\textsuperscript{13}

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

\textsuperscript{13} Caverject® PI, Revised 08/2009.
Penile Implants

An option for men who have tried other treatments without success.

- On the market for over 30 years
- Over 300,000 implants to date
- High patient and partner satisfaction rates reported in clinical studies

17 European Society for Sexual Medicine (ESSM) Website, downloaded 1/8/09.
Patient Satisfaction with ED Treatments in one Clinical Study

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.

Penile Implant* Recommended by Patients & Partners\textsuperscript{15}

Implants are Highly Recommended

- 93% of patients would recommend to others
- 90% of partners would recommend to other couples in similar situations

\*Ambicor\textsuperscript{®} two-piece inflatable penile prosthesis.

Types of Penile Implants

One-Piece Non-Inflatable  Two-Piece Inflatable  Three-Piece Inflatable
Three-Piece Inflatable Penile Implant

Product Characteristics

- Totally concealed in body
- Device is inflated to provide rigidity and deflated for concealment
- Erection longevity is controllable
- When deflated, the cylinders are soft and flaccid
- Expands in girth (all AMS 700® cylinders) and length (AMS 700 LGX® and Ultrex® cylinders)
- AMS 700 with InhibiZone® is the only inflatable penile prosthesis with clinical evidence showing a significant reduction in the rate of revision due to infection\textsuperscript{14}

\textsuperscript{14} Data on file at AMS - D970012/S065
Three-Piece Inflatable Penile Implant

Adverse Events

• Will make latent natural or spontaneous erections as well as other interventional treatment options impossible

• If an infection occurs, the prosthesis may have to be removed

• May cause the penis to become shorter, curved or scarred

• There may be mechanical failures of the prosthesis

• Urogenital pain (typically associated with healing process)

• For a complete list of risks associated with penile prostheses, refer to the specific device labeling.
Summary: Penile Implant Surgery

- Penile implants have been used for over 30 years
- Penile implants may be an option for men who fail less invasive approaches to ED treatment
- Penile implants can offer satisfaction for patients and partners as reported in clinical trials\textsuperscript{15,16}

Patient Education Materials

- Patient Education Brochure
- www.EDCure.org
Insurance Coverage of IPPs

- The Centers for Medicare and Medicaid (CMS) has a National Coverage Decision (NCD) which includes the implementation of a penile prosthesis as a treatment alternative for erectile dysfunction when medically necessary.

- Private payer coverage for penile prosthesis varies based upon insurance company and patient-specific benefit plans.
Why is it important to understand the subspecialty of prosthetic urology?

• Not every urologist is a prosthetic urologist
• Low prevalence of prosthetic urologists
• 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 a satisfying solution to erectile dysfunction can be a life-changing event for many men and their partners
The AMS 700® Series Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700 with InhibiZone®) have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), urogenital edema, urogenital ecchymosis, urogenital erythema, reservoir encapsulation, patient dissatisfaction, auto-inflation, mechanical malfunction, and impaired urination.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

Rx Only.
The AMS Ambicor® Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), patient dissatisfaction, mechanical malfunction, auto-inflation, penile curvature or sensation change, urogenital hematoma, urogenital edema, and infection.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

Rx Only.
The AMS Spectra® Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantations surgery. These devices are contraindicated in patients who: have active urogenital infections or active skin infections in the region of surgery; patients whose proximal corporal length measurements is less than the proximal rigid section of the Spectra cylinders, or whose total intracorporal length is not within the range of 12cm to 27.5cm; patients who require repeated endoscopic procedures; or patients who have compromised tissue and as a result cannot withstand constant pressure. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to: infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, adverse tissue reaction, allergic reaction, pain, urinary obstruction, and silicone particle migration.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

Rx Only.