Erectile dysfunction: unmet needs

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The numbers

- >80,000/million/year
- >43,000/million/year moderate/severe ED
- >30,000/million/year with moderate/severe vasculogenic ED

MMAS data

Aging population

Nature Reviews | Drug Discovery
Treatment options for ED

1. Viagra
2. Levitra
3. Cialis
4. Injection therapy
5. Penile implant
PDE-5 inhibitors: unmet needs

- Phosphodiesterase type 5 (PDE5) inhibitors are currently the first choice treatment option for ED by most physicians and patients due to their high efficacy rates and favourable safety profiles.

- Despite the fact that more than 100 million ED patients have been treated successfully worldwide with PDE5i several issues remain to be addressed:
  - Drop-out rates of even > 50%.
  - Patients with severe neurologic damage, diabetes mellitus, or severe vascular disease may be resistant to PDE5i.

- Patients must be aware of all treatment options since no ideal treatment exists and physicians must offer personalized medicine to their patients in the future.

- The development and adaptation of a patient-centered care model in sexual medicine will increase efficacy and safety of current and future treatments.

10-Year Analysis of Adverse Event Reports to the Food and Drug Administration for Phosphodiesterase Type-5 Inhibitors

Gregory Lowe, Raymond A. Costabile: JSM online 2011
Adherence to oral PDE-5i

- The majority of published data indicates that between 30% and 60% of initially successfully treated and satisfied men stop refilling their medication prescriptions.
- A significant proportion of discontinuations occur within one year of treatment initiation and many men do not even fill a second prescription.
- Discontinuation rates are, of course, higher and abandonment of treatment occurs earlier in patients with suboptimal treatment response.
- Factors that have been associated with a higher probability of discontinuing treatment include age over 60 years, the presence of comorbidities as evidenced by the use of incontinence products, insulin, or antidepressants and severe ED (lower IIEF-5 scores).

- Nevertheless it is clear that efficacy is only one of the factors influencing adherence to treatment: discontinuation rates are high even if ED is successfully managed.
- Given the efficacy and safety of all available PDE-5 inhibitors, it seems that patient education and understanding of their beliefs, practices, needs and expectations is the only way to find the right treatment and improve adherence to long-term use.

Speed is important!

Time to Sexual Intercourse*:
~80% of patients have sex in first 2 hours

*Giuliano et al. EUA 2006, Timing of sexual intercourse in erectile dysfunction patients treated with the three available PDE-5 inhibitors. The ECOUTE study.
Hardness is important!

The Erection Hardness Score
A self-assessment tool

<table>
<thead>
<tr>
<th>GRADE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Penis is larger but not hard</td>
</tr>
<tr>
<td>2</td>
<td>Hard but not hard enough for penetration</td>
</tr>
<tr>
<td>3</td>
<td>Hard enough for penetration but not completely hard</td>
</tr>
<tr>
<td>4</td>
<td>Completely hard and fully rigid</td>
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The 'effectiveness' scale—therapeutic outcome of pharmacologic therapies for ED: an international consensus panel report

**Clinical trials in ED are generally characterized by:**

1. Motivated patients, with high compliance in treatment administration and reporting of results.

2. Rigorous criteria for inclusion/exclusion, administration and evaluation.

3. Narrow emphasis on measurable results from the specific treatment under study.

**In contrast, clinical practice of ED is characterized by:**


2. Variability among patients in medical and psychological comorbidities, degree of compliance and consistency of reported results.

3. A broad range of possible approaches for managing ED (including counseling and other first- or second-line therapies).

The 'effectiveness' scale: an international consensus panel report

Definition of success of potential ED therapies
focus group
healthy male volunteers (n=52)

They want: “cure, pleasure and partner satisfaction”

Outcome variables of ED treatments that were highly valued by men when choosing among pharmacotherapy, vacuum devices and surgical procedures:
- naturalness,
- risk,
- partner preferences,
- reversibility and
- convenience of each potential therapy

The ideal treatment

“Ideally, ED therapy should be “simple, non-invasive and non-painful with a high success rate and few minor side effects”.

The treatment
The problem I

First stage of disease
The problem II

First stage of disease

Blood vessels get narrower

Treatment lets blood vessels relax
Erectile mechanism: from the vessel to neurotransmitters
Boys may have no chance, men DO!

Honesty is the best policy
IGNORANCE
Knowledge is power
BAD
Always be prepared
NEVER
ED: the unmet needs

Lack of efficacy
- Fast-acting drug (<30min)
- 30-50% non-responders
- post-prostatectomy

Unable to get it
- Adverse events from PDE5i
- Contraindication to PDE5i
- Drop-out from PDE5i (50%)

Personal issues
- Looking for “natural” solution
- Unsatisfactory hardness
- Looking for cure
- Cost issues
Men will always consider better erection!
New drugs
New therapies?
Why be Unique...
If you can't fly?

Thank you!