



# ED Pharmacotherapy: Take-Home Messages

Raanan Tal, MD

Israel

# Main Topics

- PDE5I – What's new?
- Low intensity shock wave therapy (LI-SWT)
- 5ARI and persistent ED

# PDE5i – What's new?

- 6 podium sessions
- 7 moderated posters
- 10 unmoderated posters

# Avanafil – The Next Generation PDE5i?

## (035, 186, 188)

- Avanafil
  - T<sub>max</sub> 30-45 min
  - FDA approved since April 2012
- DiDonato et al. (035)
  - 15 min response:
    - Diabetics & non diabetics – 60%
    - Post NSRP – 36%
  - Well suited for on-demand use
- Park et al. (186), Belkoff et al. (188)
  - Effective dose: 100mg, 200mg
  - Effective in mild to severe ED

# PDE5i – New Preparation?

- Rubio-Aurioles et al. (037) – “Viagra Jet” (Chewable)
  - Subjective perception
    - Greater efficacy
    - Rapid onset
    - Longer duration
    - Prolonged erections
    - Questionable taste
  - IIEF, EHS
    - No significant differences compared with the standard oral tablet

# PDE5i – Indications & Dosing

- BPH/LUTS - Giuliano et al. (032)
  - 511 men with BPH/LUTS, 309/511 – ED
  - Tadalafil 5mg, vs. tamsulosin 0.4mg vs. placebo
  - Results
    - IIEF OF, ejaculation, IS, OS:  
tadalafil>placebo>tamsulosin
- BPH/LUTS
  - “Bad guys”:  $\alpha$ -blockers, 5ARI, TURP
  - The “good guy”: PDE5i

# PDE5i's



## Take Home Messages:

1. Avanafil 100mg, 200mg

- Effective and well tolerated
- Very specific
- Rapid onset of action – 15 min
- No food interaction
- Well suited for on-demand use

2. Chewable Viagra (“Viagra Jet”) – subjective superiority

3. BPH/LUTS:

$\alpha$  blockers, 5ARI, surgery → sexual function side-effects  
tadalafil → sexual function benefits

# Low Intensity Shock Wave Therapy (LI-SWT)

- 3 studies
  - 2 - Vardi et al, Israel (031, 184)
  - 1- Hisasue et al, Japan (036)
- Vardi (031):
  - 60 men, vasculogenic ED, PDE5i responders
  - The first blind RCT
  - At 1 month:
    - IIEF-EFD increase – 6.7 (vs. 2.9)
    - 65%  $\geq$ 5 point increase (vs. 25%)
    - No adverse events



# Low Intensity Shock Wave Therapy

- Vardi (184):
  - 124 men, heterogeneous group (ED etiology & severity, PDE5i response)
  - A summary re-analysis of previous studies
  - At 6 months:
    - 61% - clinically significant improvement
    - Improvement across all ED severities, PDE5i responders and non-responders and in cardiovascular and diabetic patients
- Hisasue : 14 men, improved erectile function at 4 weeks

# Low Intensity Shock Wave Therapy



## Take Home Messages:

1. LI-SWT - a promising first ED cure?
2. Who is the ideal candidate? (microvascular damage?)
3. Who will not respond to LI-SWT? (PD? Post-RP?)
4. Ideal Dosing?
5. AE/toxicity?
6. Durability?
7. Need for:
  - Large high quality studies
  - Longer term results
  - Multi-institutional data
  - Animal data

# 5ARI and persistent ED

- Tal et al. (033)
  - 39 men, 5ARI past users
    - A: baldness, (Propecia), B: LUTS/BPH (Proscar, Avodart)
  - Persistent ED after drug discontinuation
  - Results: normal Doppler ultrasound in group A, and in 6/8 in group B
- Hartzell et al. (067)
  - 13 men (Aug 2010-April 2012) with persistent side effects
  - Low sex drive (77%), ED (73%), decreased penile sensitivity (54%), loss of morning erections (31%), muted orgasm (23%)
  - Depression & anxiety (77%), emotional numbness (69%)

# 5ARI and persistent ED



## Take Home Messages:

1. Adverse effects may be sexual, & emotional
2. DUS findings do not explain ED after 5ARI
3. Inform about possible persistent sexual side-effects
4. Continue research



**Have a safe trip back home!**