Helping Men Utilize ED Treatments

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Disclosure

- There are no financial disclosers to report
Introduction

• All treatments for prostate cancer impact sexual functioning$^1$
  – Only 16% of men get back to their baseline erections

• ED is related to distress:
  – ED is related to greater depressive symptoms$^2$
  – Bother related to ED does not dissipate$^3$
  – ED can increase relationship tension$^4$

• Effective treatments for erectile dysfunction (ED) available$^5$

• Penile rehabilitation programs post surgery$^6$
  – Early intervention
  – Medication assisted erections 2 to 3 times/week

Men Avoid & Drop-out of ED Treatment

- Many drop out of treatment
  - 50% of PDE5i users\textsuperscript{1}
  - 50% of injection users\textsuperscript{2}

- Self-report injection use\textsuperscript{3}
  - Only 60% continue at 4 months
  - Only 33% at a rate suggested for rehabilitation

- Syringe count injection use\textsuperscript{4}
  - Mean injections/week: 0.9
  - Only 10% at a rate suggested for rehabilitation

\textsuperscript{1}IMS Health, 2001; \textsuperscript{2}Sundaram et al., Urology, 1997; \textsuperscript{3}Nelson et al., JSM, 2013; \textsuperscript{4}Nelson et al., SMSNA, 2015
Pilot of Intervention to Improve Compliance with an Erectile Rehabilitation Program
Acceptance and Commitment Therapy

• Define important values
• Accept emotional pain or barriers to achieving valued activities
  − Acknowledge the distress
  − Willingness to experience the emotional distress
• Emotional processing of psychological distress
  − “Exposure” therapy
• Commitment
Phases of Intervention Development

• Phase I:
  – Qualitative study to help inform pilot intervention

• Phase II:
  – Pilot intervention using Acceptance & Commitment Therapy (ACT) concepts to improve compliance with penile rehabilitation
  – Aims: Feasibility and Efficacy
Qualitative Study: Cycle of Frustration and Avoidance

- Disappointment/shame related to ED
  - “I’m not a man”
  - Distress and depressive symptoms

- Fear/anxiety of entering into a sexual situation
  - Fear of not having a firm erection
  - “Injections are a turn-off”
  - “The whole process is humiliating”

- Avoidance of sexual situations

- Loss of valued life experience

- Increased frustration/distress/depression
ACT-ED Intervention

- Coaching vs. Therapy
- Explore importance of sexuality
- Accept short-term anxiety for long-term goal
  - Listen to patients’ “predictions” about injections
  - Willingness to experience anxiety and frustration
- Defuse anxiety and frustration
  - Cognitive/emotional processing
  - Humor
  - Focus on physical sensations in sexual situation
- Discuss Barriers and Solutions
- Commitment
  - Set injection target
Willingness

Courage is simply the willingness to be afraid and act anyway.”
– Robert Anthony
Pilot Intervention

• Randomized:
  - Injection Training + ACT-ED
  - Injection Training + Nurse Practitioner (NP) Information Phone Calls

• ACT-ED lasts 4 months
  - 4 individual sessions (in person/phone, 30-45min)
  - 3 check-in phone calls (5-10min)

• NP information phone call
  - Enhanced monitoring (EM)
  - 7 phone calls on the same schedule as ACT-ED
Pilot Intervention

• **Inclusion criteria**
  - Within 9 months post-RP
  - Had good erectile functioning pre-surgery
    • > 24 IIEF Erectile Function Domain
  - Advised to start penile injections

• **Exclusion criteria**
  - Specific injection phobia
  - A history of bipolar disorder or psychotic disorder
  - Current major depression
Primary Outcomes

• **Feasibility**
  - Acceptance rate
  - Completion rate

• **Injection Use (syringe count)**
  - Objective way to assess use of injections
Secondary Outcomes

• ED treatment satisfaction (EDITS)
• Sexual self-esteem and relationship quality (SEAR)
• Sexual bother (SB)
• Prostate cancer treatment regret
Pilot Intervention Design

60 Subjects

Baseline Assessment

ACT-ED
N = 30

NP Information Calls
N = 30

4 Month Follow-Up Post Baseline

8 Month Follow-Up Post Baseline
Primary Outcome: Feasibility

- **Acceptance rate**
  - 63% (53 out of 84)
  - 84 subjects approached
  - 63 subjects recruited
  - 53 subjects started the study

- **Completion rate for intervention group**
  - 71% (21 out of 26)
  - No difference compared to EM group
## Sample Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total N</strong></td>
<td>53</td>
<td></td>
</tr>
<tr>
<td><strong>N by Group:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>26</td>
<td>27</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean Age (years)</strong></td>
<td>60 ± 7</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>82%</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship Status:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnered</td>
<td>73%</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td><strong>Months Post-Surgery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 ± 2</td>
<td></td>
</tr>
<tr>
<td><strong>EFD w/Injections</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>24.5 ± 6</td>
<td>25.8 ± 6</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Primary Outcome: Injection Use - 4 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>Intervention</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Weekly Injection Use</td>
<td>0.9</td>
<td>1.7</td>
<td>0.001</td>
</tr>
<tr>
<td>% Adherence (&gt; 2 x weekly)</td>
<td>10%</td>
<td>44%</td>
<td>0.04</td>
</tr>
</tbody>
</table>
## Secondary Outcomes: 4 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention vs. Control</th>
<th>p</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Treatment Satisfaction (Range = 0-44)</td>
<td>↑ 6.6 points</td>
<td>0.09</td>
<td>0.71</td>
</tr>
<tr>
<td>Sexual Self-Esteem (Range = 0-100)</td>
<td>↑ 9.5 points</td>
<td>0.03</td>
<td>0.76</td>
</tr>
<tr>
<td>Sexual Bother (Range = 0-15)</td>
<td>↓ 1.2 points</td>
<td>0.20</td>
<td>0.51</td>
</tr>
<tr>
<td>Prostate Cancer Treatment Regret (Range = 0-25)</td>
<td>↓ 4 points</td>
<td>0.01</td>
<td>1.18</td>
</tr>
</tbody>
</table>

Cohen’s d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong
Primary Outcome: Injection Use - 8 Months

### Injection Use at 8 Months

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</tr>
</thead>
<tbody>
<tr>
<td>Mean Weekly Injection Use</td>
<td>0.7</td>
<td>1.2</td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td>% Adherence (≥ 2 x weekly)</td>
<td>0%</td>
<td>18%</td>
<td>0.18</td>
</tr>
</tbody>
</table>
## Secondary Outcomes: 8 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention vs. Control</th>
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<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Treatment Satisfaction (Range = 0-44)</td>
<td>↑ 5.4 points</td>
<td>0.15</td>
<td>0.61</td>
</tr>
<tr>
<td>Sexual Self-Esteem (Range = 0-100)</td>
<td>↑ 9.1 points</td>
<td>0.05</td>
<td>0.70</td>
</tr>
<tr>
<td>Sexual Bother (Range = 0-15)</td>
<td>↓ 0.9 points</td>
<td>0.40</td>
<td>0.39</td>
</tr>
<tr>
<td>Prostate Cancer Treatment Regret (Range = 0-25)</td>
<td>↓ 3.9 points</td>
<td>0.02</td>
<td>0.93</td>
</tr>
</tbody>
</table>

Cohen’s d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong
ACT-ED Intervention

• Preliminary pilot data suggests ACT-ED is:
  - Feasible
  - Effective

• Significantly increased:
  - Number of injections per week
  - Adherence to erectile rehabilitation program

• Moderate to large effects on secondary outcomes

• Novel intervention:
  - Proactively helping men regain erections and mitigating negative psychosocial implications of chronic ED
  - Integrates psychosocial with medical best practice
Pen is broken. Please use Finger!  
Thanks
Talking to Patients about ED Treatments

- Educate
- Explore and focus on importance of sexuality
- Acknowledge short-term anxiety
  - Willingness to experience anxiety and frustration
- Focus on long-term goal as opposed to short-term anxiety
- Discuss/highlight barriers
  - Ask them what will get in the way of using treatment
  - Predict they will find excuses to avoid using treatment
- Commitment
  - Set injection target
“Two of the most important things you can do as a physician are to listen to your patients and care for your patients.”

Patrick Walsh

Prostate Cancer World Congress, Cairns Australia, 2015