Sex Therapy for PE is Necessary

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Disclosures

- Dr. Althof serves as a Principal Investigator, Consultant or Member of an Advisory Board to:
  - Allergan
  - Bayer
  - Eli Lilly
  - Evidera
  - Ixchelsis
  - Palitan
  - Pfizer
  - Promescent
  - S1 Pharma
  - SSI
  - Valeant
Overview of Treatments for Premature Ejaculation

- Pharmacotherapy alone-
  - Dapoxetine in countries where it is approved
  - Off-label SSRI’s/SNRI’s
    - Chronic and as-needed dosing
  - Off-label Tramadol
  - Topical anesthetics
  - PDE5i??

- Psychotherapy/Sex Therapy/Couples Therapy alone

- Combination Pharmacotherapy and Psychotherapy
ISSM Recommended Treatments for the Different Subtypes of PE

**Lifelong PE**
- Pharmacotherapy, **Combination Psychological & Medical Therapy**

**Acquired PE**
- Treatment of underlying condition, **Psychotherapy or Behavioral Therapy**, Pharmacotherapy alone or, **Combination Psychological & Medical Therapy**

**Natural PE**
- Reassurance, Education, **Psychotherapy or Behavioral Therapy**

**Subjective PE**
- Reassurance, Education, **Psychotherapy or Behavioral Therapy**

Psychotherapy Harnesses the Power of the Mind to Teach Men a Set of Skills

1. Learn techniques to control and delay ejaculation
2. (Re)gain confidence in their sexual performance
3. Lessen performance anxiety
4. Modify rigid sexual repertoires
5. Cognitive restructuring
6. Surmount barriers to intimacy
7. Resolve interpersonal issues (that cause/maintain PE)
8. Increase communication
9. Turn conflict and useless friction into intimacy, fantasy and stimulation
10. Minimize or prevent relapse

A Controlled Study of Two Psychological Interventions

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-Treatment Mean IELT-seconds</th>
<th>Post-Treatment Mean IELT seconds</th>
<th>3 Month Follow-up Mean IELT Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral</td>
<td>57</td>
<td>472</td>
<td>490*</td>
</tr>
<tr>
<td>Waiting List</td>
<td>63</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

Outcome Studies of Behavioral Treatment

- Meta-analysis suggested that psychotherapy may not be efficacious for men with PE
  - Very few studies met the inclusion/exclusion criterion
  - Based on 4 studies, 3 of which were combination therapy

- A systematic review concluded that there is limited evidence that behavioral techniques for PE improve IELT and other outcomes and that behavioral therapies combined with drug therapies yield better outcomes than drug therapies alone

- Another systematic review concluded that behavioral approaches that include the stop–start technique and squeeze technique are more effective than a waiting-list control group

Dr. Althof’s Life Lesson

Treating PE is far more complicated than simply increasing IELT or improving the man’s subjective sense of control.
Impact of PE

- PE is associated with diminished sexual satisfaction for the patient and partner

- PE impacts on self-esteem, sexual confidence, and intimacy

- Men with PE are significantly bothered by the dysfunction

- Partners of PE men are likewise significantly bothered

- PE has detrimental effects upon relationships

- PE interferes with single men beginning new relationships

The Burden of PE on the Relationship

- Strain on relationship
  - Mistrust of partner
  - Perceived selfishness of man

- Difficulty initiating and maintaining relationships

- Dissatisfaction with sexual relationship

- Inability or lack of desire to communicate
  
  Partner has not raised the problem
  - Fears hurting man’s feelings
  - Does not know how to discuss
  - Some think it is a normal condition
  - Many think there is no solution

Treatment of PE with SSRI’s/SNRI’s

- Although controversies exist, both on demand and chronic dosing of SSRI’s/SNRI’s have been effectively used for treating PE

- Daily treatment with paroxetine 20 mg may exert the strongest delay in intravaginal ejaculatory latency time (IELT)

- Chronic dosing is favored by men with lifelong PE because it provides no interference with the spontaneity of having sex

Discontinuation/Acceptance Rates of Men with Lifelong PE Treated with Paroxetine

- Patients received 10 mg paroxetine daily for 21 days and then 20 mg as needed (taken 3–4 hours before the planned intercourse)

- Thereafter, the patients could stay with the same on-demand paroxetine 20 mg treatment or they could take paroxetine 10 mg daily for the subsequent 3 months

- Patients were evaluated both at the 3- and 6-month follow-up, and completed assessment questionnaires regarding specific reasons for eventual therapy discontinuation

- 99 consecutive men with lifelong PE enrolled in the study

- 28/99 men never began Paroxetine because:
  - 43% - feared taking a psychiatric drug
  - 36% - GP refused to prescribe off-label drug
  - 14% - Partner refused to have sex if he used an antidepressant
  - 7% - Patient not wanting to use an off-label drug

- 75% of these patients did not request an alternative therapy??
  - Remaining patients received topical anesthetic

Discontinuation/Acceptance Rates of Men with Lifelong PE Treated with Paroxetine

- Sixty-five (69.9%) of the original 93 patients started the paroxetine treatment protocol.

- By 3 months another 20 men (31%) had discontinued. The reasons for treatment discontinuation included:
  - Treatment effect below expectations (15/20, 75%)
  - Loss of interest in sex because of couple’s relational issues (3/20, 15%)
  - Treatment emergent side effects (2/20, 10%), e.g. nausea and irritability in one patient each

- At 6-months no other subject had discontinued therapy.

- The mean IELT was further improved as compared with the 3-month assessment (namely, 5.1 [1.0] vs. 4.2 [0.9] minutes).

- When interviewed regarding their favored treatment modality, daily paroxetine 10 mg was chosen by 35 (77.8%) of the 45 patients who completed the study protocol, and on-demand paroxetine 20 mg by 10 (22.2%).

Dapoxetine Treatment in Patients With Lifelong Premature Ejaculation: The Reasons of a “Waterloo”

- 120 consecutive potent patients were enrolled in a prospective phase II Dapoxetine study
  - Each subject underwent a detailed medical and sexual history, intravaginal ejaculatory latency time (IELT), International Index of Erectile Function (IIEF), and complete physical examination.

- Patients received dapoxetine (30 mg on demand) and unresponsive patients had their dose increased to 60 mg

- Subjects were evaluated at 1, 3, 6, and 12 months, and completed a multiple-choice global assessment questionnaire regarding specific reasons for eventual therapy discontinuation

Dapoxetine Treatment in Patients With Lifelong Premature Ejaculation: The Reasons of a “Waterloo”

- Twenty-four of the patients (20%) decided not to start dapoxetine. Fear of using a “drug” was the most frequently reported reason for treatment nonacceptance (50%) and the cost of treatment was the reason for 25% of the patients.
- 96 subjects (80%) started the therapy.
  - 26% dropped out after 1 month
  - 42.7% dropped out after 3 months
  - 18.7% dropped out at 6 months
  - 2% dropped out at 12 months

- Reasons for discontinuation included:
  - Effect below expectations 24.4%
  - Cost 22.1%
  - Side effects 19.8%
  - Loss of interest in sex 19.8%
  - No efficacy 13.9%.

- 10.4% are continuing the therapy after 1 year

Combination Therapy- The Essential Premise

- Either concurrently or in a stepwise fashion clinicians combine pharmacotherapy with short-term psychological-behavioral-and/or couple’s interventions

- Several studies report on combined pharmacological and behavioral treatment for PE

- Each study reported on a different medication- sildenafil, citalopram, clomipramine. Pharmacotherapy was given in conjunction with a behavioral treatment and compared to pharmacotherapy alone

- In all the studies combination therapy was superior to pharmacotherapy alone on either IELT and/or the Chinese Index of Premature Ejaculation

Results of Combination Therapy

<table>
<thead>
<tr>
<th>PEDT Score</th>
<th>Baseline</th>
<th>4-weeks</th>
<th>12-weeks</th>
<th>24-weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>20</td>
<td>18</td>
<td>16</td>
<td>15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group B</td>
<td>19</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
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<th>Mean IELT</th>
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<th>24-Weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>85</td>
<td>85</td>
<td>131</td>
<td>160</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group B</td>
<td>92</td>
<td>138</td>
<td>233</td>
<td>371</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Group A- Dapoxetine 30mg alone
Group B- Dapoxetine 30mg + Psychological Intervention

Is Sex Therapy Necessary?

- Yes, because it teaches the man a set of skills to delay and control ejaculation

- Yes, because it may ameliorate the psychosocial issues associated with PE as well as the burden of PE on the partner and relationship

- Yes, because treatment with SSRI’s, while efficacious, is not continued by the vast majority of patients for whom they are prescribed
  - No real world data on tramadol or topical anesthetics

- Yes, because in several studies combination pharmacotherapy and psychotherapy has been shown to be the most effective treatment intervention
  - Despite the evidence practice patterns do not seem to be changing