Treatment Induced Erectile Dysfunction

Gerald Brock
Professor of Surgery
University of Western Ontario
Should you believe in Rehab?
Should you believe in Rehab?

Avoidance
Education related to effects
Understand the treatment approaches
Penile Innervation

Pudendal nerve (somatic)

Cavernous nerve (autonomic)
Should you believe in Rehab?

- Understand pathology
- Know risks / benefits of Tx
- Be able to transfer knowledge
Should you be offering Sexual Rehabilitation to your RRP patients?
My View

- ED common after RP
- ED - decreased QOL
- Penile rehabilitation associated with financial expenditure
- Penile rehabilitation is being used by clinicians
- In discussion with Patients the option should be advanced
A Good Idea
A Good Idea....

IVF........................................

Let's Do a Real Life Study
One that looks at a natural setting with men like we all see.
Prediction of Erectile Function Following Treatment for Prostate Cancer
Figure 1. Model-Predicted Probability of Functional Erections Suitable for Intercourse 2 Years After Radical Prostatectomy
Platinum Priority – Review – Prostate Cancer
Editorial by Peter C. Albertsen on pp. 365–367 of this issue

**Systematic Review and Meta-analysis of Studies Reporting Potency Rates After Robot-assisted Radical Prostatectomy**

Vincenzo Ficarra\(^{a,b,*}\), Giacomo Novara\(^{a}\), Thomas E. Ahlering\(^{c}\), Anthony Costello\(^{d}\), James A. Eastham\(^{e}\), Markus Graefen\(^{f}\), Giorgio Guazzoni\(^{g}\), Mani Menon\(^{h}\), Alexandre Mottrie\(^{h}\), Vipul R. Patel\(^{i}\), Henk Van der Poel\(^{i}\), Raymond C. Rosen\(^{k}\), Ashutosh K. Tewari\(^{l}\), Timothy G. Wilson\(^{m}\), Filiberto Zattoni\(^{a}\), Francesco Montorsi\(^{g}\)
Table 2 – Potency rates after robot-assisted radical prostatectomy stratified according to difficult cases (obese patients, large prostate) or surgeon experience (learning curve)

<table>
<thead>
<tr>
<th>First author</th>
<th>Cases, n</th>
<th>Surgical technique</th>
<th>Study design</th>
<th>Potency definition</th>
<th>Data collection</th>
<th>3 mo, %</th>
<th>6 mo, %</th>
<th>12 mo, %</th>
<th>24-36 mo, %</th>
<th>Muhall criteria fulfilled</th>
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<tbody>
<tr>
<td>Wiltz, 2009 [33]</td>
<td>BMI &lt;25 (155) Monolateral (240) Prospective case series</td>
<td>ESI Validated questionnaire</td>
<td>48 58 68 80</td>
<td>7</td>
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<tr>
<td></td>
<td>BMI 25-30 (312) Bilateral (632)</td>
<td>Interfacial</td>
<td>44 52 60 79</td>
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<tr>
<td></td>
<td>BMI &gt;30 (165) Clips (bilateral cysture)</td>
<td>Interfacial</td>
<td>40 47 49 56</td>
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<tr>
<td>Mokri, 2010 [34]</td>
<td>BMI &lt;25 (270) Not reported Prospective case series</td>
<td>SHIM &gt;16 Validated questionnaire</td>
<td>70 74 86 – 3</td>
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<tr>
<td></td>
<td>BMI 25-30 (600)</td>
<td>65 75 84 –</td>
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<td>BMI &gt;30 (242)</td>
<td>62 74 82 –</td>
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<tr>
<td></td>
<td>BMI &gt;10 (54)</td>
<td>3 11 25 –</td>
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<tr>
<td>Zum, 2009 [36]</td>
<td>Case 1-300 (525) Bilateral NS Prospective case series</td>
<td>ESI Validated questionnaire</td>
<td>43 47 61 – 5</td>
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<tr>
<td></td>
<td>Case 301-500 (63) Interfacial</td>
<td>43 51 63 –</td>
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<tr>
<td></td>
<td>Case 501-120 (62) Clips (bilateral cysture)</td>
<td>44 54 65 –</td>
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</table>
Back to Basline: Erectile Function Recovery after Radical Prostatectomy from the Patients’ Perspective

Christian J. Nelson, PhD,* Peter T. Scardino, MD,† James A. Eastham, MD,‡ and John P. Mulhall, MD†

*Department of Psychiatry and Behavioral Sciences, Memorial Sloan-Kettering Cancer Center, New York, NY, USA;
†Reproductive Medicine Program, Urology Service, Memorial Sloan-Kettering Cancer Center, New York, NY, USA;
‡Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY, USA

Conclusions. Twenty-two percent of the entire sample and 16% of the men with functional (EFD ≥ 24) baseline erections returned to BTB EF without the use of medication. Only 4% of men who were ≥60 years old with functional erections pre-surgery achieved BTB EF. Although gaining partial EF is also important, men pre-RP should be educated on EFR and the chance of “back to baseline” EF. Nelson CJ, Scardino PT, Eastham JA, and Mulhall JP. Back to baseline: Erectile function recovery after radical prostatectomy from the patients’ perspective. J Sex Med 2013;10:1636–1643.
## Table 2  Percent achieving back to baseline erectile function recovery

<table>
<thead>
<tr>
<th></th>
<th>With/without PDE5i at 24 months (%)</th>
<th>95% CI</th>
<th>Not using PDE5i at 24 months (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total sample</strong></td>
<td>N = 180</td>
<td>43</td>
<td>36–51%</td>
<td>22</td>
</tr>
<tr>
<td><strong>Baseline EFD ≥ 24</strong></td>
<td>N = 132</td>
<td>36</td>
<td>28–44%</td>
<td>16</td>
</tr>
</tbody>
</table>

EFD – Erectile Function Domain; PDE5i – phosphodiesterase type 5 inhibitor.
What is Rehab

Rehabilitation involves the use of a medication, combination of medications, devices (alone or in combination with medication) in the early stages after RP. The goal of rehabilitation is to maximize preservation of all components of the local erectile mechanism and optimize recovery of erectile function.
Erectile Function Rehabilitation after Radical Prostatectomy: Practice Patterns among AUA Members

Raanan Tal, MD, Patrick Teloken, MD, and John P. Mulhall, MD
Sexual and Reproductive Medicine Program, Urology Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY, USA

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of post-RP penile rehabilitation surveys</th>
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<tbody>
<tr>
<td></td>
<td>Present study</td>
</tr>
<tr>
<td>Population surveyed</td>
<td>AUA members</td>
</tr>
<tr>
<td>No. of responders</td>
<td>618</td>
</tr>
<tr>
<td>Sexual medicine specialists</td>
<td>90%</td>
</tr>
<tr>
<td>Urologic oncology specialists</td>
<td>91%</td>
</tr>
<tr>
<td>Perform RP</td>
<td>89%</td>
</tr>
<tr>
<td>Rehabilitation rate</td>
<td>86%</td>
</tr>
<tr>
<td>Preferred intervention</td>
<td>PDE5i</td>
</tr>
<tr>
<td>Preferred frequency</td>
<td>Daily/3 times weekly</td>
</tr>
<tr>
<td>Preferred initiation timing</td>
<td>Immediately/after catheter removal</td>
</tr>
<tr>
<td>Preferred rehabilitation duration</td>
<td>12–18 months</td>
</tr>
<tr>
<td>Perform rehabilitation only on selected patients</td>
<td>57%</td>
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<th>Present study</th>
<th>Teloken et al. 2009</th>
<th>Giuliano et al. 2006</th>
</tr>
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<tbody>
<tr>
<td>Population surveyed</td>
<td>AUA members</td>
<td>ISSM members</td>
<td>French urologists</td>
</tr>
<tr>
<td>No. of responders</td>
<td>618</td>
<td>301</td>
<td>535</td>
</tr>
<tr>
<td>Sexually medicine specialists</td>
<td>90%</td>
<td>65%</td>
<td>N/A</td>
</tr>
<tr>
<td>Urologic oncology specialists</td>
<td>91%</td>
<td>44%</td>
<td>N/A</td>
</tr>
<tr>
<td>Perform RP</td>
<td>89%</td>
<td>60%</td>
<td>98.5%</td>
</tr>
<tr>
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<td>86%</td>
<td>87%</td>
<td>54%</td>
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<td>Preferred intervention</td>
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<td>ICI</td>
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<tr>
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<td>Daily/3 times weekly</td>
<td>Daily/3 times weekly</td>
<td>N/A</td>
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<tr>
<td>Preferred initiation timing</td>
<td>Immediately/after catheter removal</td>
<td>Immediately/after catheter removal</td>
<td>Within 3 months</td>
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<tr>
<td>Preferred rehabilitation duration</td>
<td>12–18 months</td>
<td>Less than 12 months</td>
<td>12 months</td>
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<tr>
<td>Perform rehabilitation only on selected patients</td>
<td>57%</td>
<td>67%</td>
<td>62%</td>
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</tbody>
</table>
Rehabilitation Strategies Used
ISSM Survey

- PDE-5i: 95%
- Vacuum: 30%
- ICI: 75%
- Intra-urethral: 10%
Postprostatectomy ED: Proposed Mechanism

- Arterial injury
  - Reduced/absent erection
  - Prolonged venous \[ pO_2 \]
  - TGF-\[\beta\] overexpression
  - Excess collagen production
  - Structural alterations
- Anxiety/stress
  - Incomplete corporal muscle expansion
  - Subtunical venule decompression
  - Venous leak
- Neural injury
  - Erectile tissue apoptosis
PG Production in Varied Oxygen States

Histological Alterations in Erectile Tissue

Pre-op 2 Months After RP

Elastic and collagen fibers in 19 patients before, and 2 and 12 months after radical prostatectomy

<table>
<thead>
<tr>
<th></th>
<th>Mean Fibers ± SD</th>
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<tbody>
<tr>
<td></td>
<td>Elastic/High Power Field</td>
</tr>
<tr>
<td>Before</td>
<td>129.32 ± 13.13</td>
</tr>
<tr>
<td>After 2 mos</td>
<td>80.80 ± 23.26</td>
</tr>
<tr>
<td>After 12 mos</td>
<td>44.20 ± 11.58</td>
</tr>
</tbody>
</table>

Before vs after 2 and 12 months, and after 2 vs 12 months p <0.0003.

Iacono F et al. J Urol, 163:1673-76, 2005
Reduced O₂ Tension Inhibits Erectogenic Mechanisms

- Oxygen tension directly impacts physiological function and corpus cavernosum structure
- O₂ is required for NO production and normal endothelial function
PDE5i & Systemic Hypoxia-Induced ED

Intracavernosal pressure (ICP) vs. Pudendal Flow (ml/min)

- 21% FiO2
- 20% FiO2
- 19% FiO2
- 18% FiO2

Nerve stim vs. PDE5i

Vardenafil Prevents Penile Fibrosis and Smooth-Muscle Cell Loss After Denervation in the Rat

- Smooth muscle/collagen ratio was normalized (Masson trichrome staining)
- Smooth-muscle cell content was normalized (smooth-muscle cell marker staining)
- Erection response was maintained (papaverine injection, dynamic infusion cavernosometry)

*30 mg/L in drinking water x 45 days.

Corporal Smooth Muscle Apoptosis
Impact of Sildenafil
ERECTILE DYSFUNCTION AFTER RADICAL PROSTATECTOMY: HEMODYNAMIC PROFILES AND THEIR CORRELATION WITH THE RECOVERY OF ERECTILE FUNCTION

JOHN P. MULHALL, RON SLOVICK, JAMES HOTALING, NAID AVIV, ROLANDO VALENZUELA, W. BEDFORD WATERS AND ROBERT C. FLANigan

From the Department of Urology, Loyola University Medical Center, Stritch School of Medicine, Maywood, Illinois
ERECTILE DYSFUNCTION AFTER RADICAL PROSTATECTOMY: HEMODYNAMIC PROFILES AND THEIR CORRELATION WITH THE RECOVERY OF ERECTILE FUNCTION

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- Anxiety/stress
  - Incomplete corporal musc expansion
  - Subtunical venule decompression
  - Venous leak

- Neural injury
  - Erectile tissue apoptosis
Animal Data

- Muller A et al. The functional and structural consequences of cavernous nerve injury are ameliorated by sildenafil citrate. J Sex Med, 2008
- Kovanecz I et al. Long-term continuous sildenafil treatment ameliorates CVOD induced by cavernosal nerve resection in the rats. IJIR, 2008; 20:202
- Ferrini M et al. Vardenafil prevents fibrosis and loss of smooth muscle after bilateral cavernosal nerve resection in the rat. Urology, 2006; 68:429
- Vignozzi L et al. Effect of chronic tadalafil administration on penile hypoxia induced by cavernous neurotomy in the rat. J Sex Med; 2006; 3:419
- Kovanecz I et al. Chronic daily tadalafil prevents the corporal fibrosis and venocclusive dysfunction that occurs after cavernosal nerve resection. BJUI; 2008; 101:203
- Lysiak JJ et al. Tadalafil increases AKT and extracellular signal-related kinase 1/2 activation and prevents apoptotic cell death in the penis following denervation. J Urol, 2008; 179:779
Post-RP Nightly Sildenafil Study

Study Design

Preoperative assessment (1-4 weeks) | Recovery period (4 weeks) | Postoperative drug treatment (36 weeks) | Drug-free postoperative assessment (8 weeks)

Surgery | Start drug | End drug

**Results**

*Responders were defined as those having a combined score of 8 for IIEF Q3+4 and a positive response to GEQ (Over the past 4 wks, have your erections been good enough for satisfactory sexual activity)*

Choosing the Best Candidates for Penile Rehabilitation after Bilateral Nerve-Sparing Radical Prostatectomy

Alberto Briganti, MD, Ettore Di Trapani, MD, Firas Abdollah, MD, Andrea Gallina, MD, Nazareno Suardi, MD, Umberto Capitanio, MD, Manuela Tutolo, MD, Niccolò Passoni, MD, Andrea Salonia, MD, Valerio DiGirolamo, MD, Renzo Colombo, MD, Giorgio Guazzoni, MD, Patrizio Rigatti, MD, and Francesco Montorsi, MD

ED Rates post RRP

![Graph showing cumulative percentage of patients recovering EF over time to EF recovery](image)
ED post RRP with Rehab

Log rank $P<0.001$

Use of PDE5-I
$(N= 242, 55.6\%)$

No therapy
$(N= 193, 44.4\%)$

<table>
<thead>
<tr>
<th></th>
<th>% 1-yr (no at risk)</th>
<th>% 2-yr (no at risk)</th>
<th>% 3-yr (no at risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No TX</td>
<td>36% (39)</td>
<td>38% (40)</td>
<td>38% (33)</td>
</tr>
<tr>
<td>TX</td>
<td>60% (66)</td>
<td>72% (25)</td>
<td>72% (19)</td>
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</table>

Percentage of patients recovering EF

Time to EF recovery (months)
Moderate Risk Group
Effects of Tadalafil (TAD) Treatment on Erectile Function Recovery post Bilateral Nerve-Sparing Radical Prostatectomy (nsRP)

Gerald Brock¹, Francesco Montorsi², Jens-Uwe Stolzenburg³, John Mulhall⁴, Ignacio Moncada⁵, Hiten Patel⁶, Daniel Chevallier⁷, Kazimierz Krajka⁸, Carsten Henneges⁹, Ruth Dickson¹⁰, Hartwig Büttner⁹

¹University of Western Ontario, London, Canada; ²Istituto Scientifico Universitario San Raffaele, Milan, Italy; ³Universitätsklinikum Leipzig, Leipzig, Germany; ⁴Memorial Sloan-Kettering Cancer Center, New York, USA; ⁵Hospital La Zarzuela, Madrid, Spain; ⁶University Hospital North Norway, Tromso, Norway; ⁷Hôpital Universitaire Archet 2, Nice, France; ⁸Uniwersyteckie Centrum Kliniczne, Gdansk, Poland; ⁹Lilly Deutschland GmbH, Bad Homburg, Germany; ¹⁰Lilly Canada Inc, Toronto, Canada
Study Design

**Screening**

- Tadalafil 5 mg OaD + Placebo PRN
- Placebo OaD + Tadalafil 20 mg PRN
- Placebo OaD + Placebo PRN

**Double-blind treatment**

- Tadalafil 5 mg OaD + Placebo PRN

**Drug-free Washout**

- Placebo OaD + Placebo PRN

**Open-label tadalafil 5 mg OaD**

**Abbreviations:**
- d = days
- m = months
- nsRP = bilateral nerve-sparing prostatectomy
- OaD = once a day
- PRN = pro re nata or on demand
- V = visit
- wks = weeks

**Timeline**

- V1: Baseline
- V2: Randomization
- V3: 3-20 days
- V4: 3 weeks
- V5: 2 months
- V6: 3 months
- V7: 4 months
- V8: 6 weeks
- V9: 3 months

**Events**

- Month 0: Baseline
- Month 9: Primary endpoint
- Month 10.5
- Month 13.5
Patient Disposition

ITT and Safety Population (N = 422)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
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<tr>
<td>Tadalafil OaD</td>
<td>139</td>
</tr>
<tr>
<td>Tadalafil PRN</td>
<td>142</td>
</tr>
<tr>
<td>Placebo</td>
<td>141</td>
</tr>
</tbody>
</table>

Most frequent reasons for discontinuation:
- Entry criteria not met: 23.1%
- Subject decision: 22.2%
- Adverse event: 19.4%
- Lack of efficacy: 15.7%
- Lost to follow-up: 13.0%

Abbreviations: ITT = intention-to-treat; N = total number of subjects; OaD = once a day; PRN = on-demand.
## Results: Baseline Characteristics

<table>
<thead>
<tr>
<th>nsRP approach, n (%)</th>
<th>Tadalafil OaD (N = 139)</th>
<th>Tadalafil PRN (N = 143)</th>
<th>Placebo (N = 141)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total nerve sparing score (range 1-4)(^1), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perfect (2)</td>
<td>117 (84.2)</td>
<td>116 (81.1)</td>
<td>113 (80.1)</td>
</tr>
<tr>
<td>Not perfect (&gt;2)</td>
<td>22 (15.8)</td>
<td>27 (18.9)</td>
<td>28 (19.9)</td>
</tr>
</tbody>
</table>

Abbreviations: nsRP = bilateral nerve-sparing prostatectomy; N = total number of subjects; n = number of available subjects; OaD = once a day; PRN = on-demand; SD = standard deviation.  
IIEF-EF: Mean Change from Baseline

Abbreviations: CI = confidence interval; IIEF-EF = International Index of Erectile Function - erectile function domain; LS = least square; MMRM = mixed model for repeated measures; OaD = once a day; PLC = placebo; PRN = “pro re nata” or on-demand; TAD = tadalafil.
Abbreviations: CI = confidence interval; IIEF-EF = international index of erectile function-erectile function domain; LS = least square; MMRM = mixed-model for repeated measures; OaD = once a day; PLC = placebo; PRN = "pro re nata" or on-demand; TAD = tadalafil.

** p<0.001 (TAD OaD vs PLC, MMRM)
SEP-3: Yes Responses

Abbreviations: CI = confidence interval; IIEF-EF = International Index of Erectile Function – Erectile Function Domain; MMRM = mixed model for repeated measures; n.s. = not significant; OaD = once a day; PLC = placebo; PRN = “pro re nata” or on demand.
Change in Penile Length (ANCOVA)

<table>
<thead>
<tr>
<th>Group difference</th>
<th>LS mean change, mm [95% CI]; p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OaD vs. PRN</td>
<td>5.7 [1.93, 9.40]; 0.003</td>
</tr>
<tr>
<td>OaD vs. PLC</td>
<td>4.1 [0.35, 7.83]; 0.032</td>
</tr>
<tr>
<td>PRN vs. PLC</td>
<td>-1.6 [-5.25, 2.10]; 0.399</td>
</tr>
</tbody>
</table>

ANCOVA = analysis of covariance; CI = confidence interval; IIEF-EF = international index of erectile function-erectile function domain; LS = least square; n.s. = not significant; OaD = once a day; PLC = placebo; PRN = "pro re nata" or on demand; RT = randomized treatment.
Conclusions

- Strong animal and evolving human evidence of efficacy for sexual rehabilitation
- Widespread use and acceptance
- Only downside is cost
SOP Conservative (Medical and Mechanical) Treatment of Erectile Dysfunction

Hartmut Porst, MD,* Arthur Burnett, MD, MBA, FACS,† Gerald Brock, MD, FRCSC,‡ Hussein Ghanem, MD,* Francois Giuliano, MD,§ Sidney Giina, MD,** Wayne Hellstrom, MD, FACS, †† Antonio Martin-Morales, MD,*‡ Andrea Salonia, MD,*§ Ira Sharlip, MD,†† and the ISSM Standards Committee for Sexual Medicine

ISSM Standards Committee for Sexual Medicine
Sub-Committee Male Sexual Dysfunction
Chapter: Medical/Conservative Treatment in ED, Priapism, and Peyronie's Disease

Einmalystem zur Verabreichung von Alprostadi (PGE1) in die Harnröhre
Injecting Alprostadil into the cavernous body.
Specific endocrine therapy
- T-substitution
- Prolactin inhib.

Sexual therapy an option,
PDE-5-inhibitors,
eventually vacuum therapy

PDE-5 Inhibitors
or vacuum therapy

Cardiologic council

Sexual activities permitted

Adding PDE-5 Inhib.

Switching to another PDE 5 inhibitor or Tadalafil daily for 2-3 months may be an option

PDE-5-inhibitors,
vacuum therapy

NON-RESPONDERS

Non-Responder
Injection-therapy

Alprostadil 20-40µg → Pap 30mg / Phentolamine 1mg → Trimix PGE1 20-40µg / Papaverine 30mg / Phentolamine 1mg

Non-Responder

Combination oral and transurethral or injection-therapy (PGE1 mono (20-40 µg, or Papaverine / Phentolamine or Trimix)

Vacuum-therapy, eventually combined with oral, intraurethral or intracavernosal therapy

Non-Responder: about 5-10% of all ED-patients
Conclusions

- Strong animal and evolving human evidence of efficacy for sexual rehabilitation
- Widespread use and acceptance
- Only downside is cost

Would you want Rehab if you had a RRP?
21st Century Rigidometer