Vacuum Therapy for Erectile Dysfunction:
ISSM 2014
Sao Paolo, Brazil

Hossein Sadeghi-Nejad, MD, FACS

Professor of Surgery in Urology
Rutgers– New Jersey Medical School
Hackensack University Medical Medical Center
Chief of Urology, VA NJ Health Care System
Historical Perspective

- 1874: John King: “glass exhauster”
- 1917: Otto Lederer patent: vac + ring
- 1960s: Geddings D. Osbon
  - Erecaid (1982 FDA)
- 1996: AUA Clinical Guidelines Panel

Mechanism of Action

- Cylinder, pump, constriction ring
- Lubrication
- 30 minute limit

Bosshardt et al., Br J Urol, 1995; 75: 786-791
Mechanism of Action
VED Application

**SLOW process**

- Pump → wait 3-5s → pump.
- Repeat till penis lifts of the bottom of the cylinder
- The release button may be used in between these steps to stretch the tissues more slowly.
Indications

ED including SCI, Post-prosthesis explant

- Pre-prosthesis placement, penile rehabilitation

- Second line therapy

- Combination therapy
  - (ICI, PDE5-Is, intraurethral, prostheses)

Survey of International Society of Sexual Medicine (ISSM) Members: Use Patterns for the Vacuum Erection Device
Thomas Facelle*, Newark, NJ, Hossein Sadeghi-Nejad, Hackensack, NJ

To what extent do you or your practice employ the VED for the following indications?

<table>
<thead>
<tr>
<th>Answer options</th>
<th>All the time</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
<th>Response count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehabilitation after RP</td>
<td>22%</td>
<td>33%</td>
<td>27%</td>
<td>8%</td>
<td>9%</td>
<td>85</td>
</tr>
<tr>
<td>ED, after PDE5i failure</td>
<td>7%</td>
<td>22%</td>
<td>50%</td>
<td>16%</td>
<td>5%</td>
<td>86</td>
</tr>
<tr>
<td>Diabetic ED</td>
<td>11%</td>
<td>16%</td>
<td>46%</td>
<td>20%</td>
<td>7%</td>
<td>85</td>
</tr>
<tr>
<td>ED, as a last option</td>
<td>4%</td>
<td>16%</td>
<td>44%</td>
<td>26%</td>
<td>10%</td>
<td>80</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>4%</td>
<td>12%</td>
<td>33%</td>
<td>37%</td>
<td>13%</td>
<td>82</td>
</tr>
<tr>
<td>ED, first line</td>
<td>1%</td>
<td>8%</td>
<td>22%</td>
<td>41%</td>
<td>28%</td>
<td>83</td>
</tr>
</tbody>
</table>

Table 1: VED Use Patterns by Indication: All Respondents that Currently Prescribe VEDs
CONCLUSIONS: Most of the respondents in this survey used the VED “All of the Time” or “Often” for post RP penile rehabilitation.

Many use VED following PDE5i failure and for diabetic patients.

Obstacles to VED use include, surprisingly for sexual health practitioners, lack of familiarity with the VED application technique and mechanism of function.
Contraindications

- Spontaneous priapism history
- Penile deformities and anomalies (relative)
- Adverse events in pts on anticoagulants:
  Similar to the general population
  Petechiae, bruising, hematoma

Limoge et al., J Urol. 1996; 155: 1276-1279
Combination Therapy: PDE5-I Nonresponders

VED + PDE5-i salvage therapy in medication nonresponders

- n=69 (min 4-6 trials highest dose PDE5i)
- mean IIEF ↑ (9.0 to 17.6)
- 79% of SEP-2 “no” responders → “yes”
- 70% of SEP-3 “no” responders → “yes”
- 74% “moderately” or “greatly” improved Global Pt Assessment Scale (GPAS)

Canguven et al., J Sex Med. 2009; 6: 2561-2567
Specific Applications: SCI

- Alternative modality to ICI & IPP
- Advocated by some as first line Rx prior to PDE5-inhibitor availability
- ~50% patient/partner satisfaction
- Decreased penile sensation MAY lead to higher complication rates (SQ hemorrhage, erosion, cellulitis, gangrene, ….)

Seckin et al., Int Urol & Nephrology, 1996; 28(2): 235-240
Denil et al., Arch Phys med Rehabil; 1996; 77(8): 750-753
Specific Applications: Peyronie’s Disease

Off label use

- Inconsistent data
- Lue 1999: 4 pts + circumferential tunical incision + circular graft + VED → satisfied with outcomes
- Use without constriction ring 10 min daily
  - 67% improved, 10% worsened, 23% no change

Lue T et al., J Urol, 1999; 161 (4): 1141-1144
Kim JH et al., J Urol 1993; 149(5)1314-1315
Specific Applications: Peyronie’s Disease

The role of vacuum pump therapy to mechanically straighten the penis in Peyronie’s disease

- 21 of 31 reduced curvature 5–25°
- 3 worse
- 7 no change

Abdel Raheem et al., BJU Int, 2010
Specific Applications
Post IPP Explantation or in Combination

- **1989 Moul:** 14 explant patients. 11 used VED.
  91% : satisfactory erections & intercourse
- **5 / 6 infection-explants successfully used VED**
- **Korenman:** similar data. Also some in combination with IPP
- **Soderdahl:** Use of VED in *combination* with implants (n=12)
  - 8 IPP, 4 SR. Increased rigidity in all. 11/12 with increased length and girth.

Moul et al; J Urol. 1989; 142 (3): 729-731
Korenman et al., J Am Ger Soc. 1992; 40 (1):61-64
Soderdahl et al., Tech Urol. 1997; 3 (2)
Revision of Penile Prosthesis Surgery after Use of Penile Traction Therapy to Increase Erect Penile Length: Case Report and Review of the Literature

Daniel J. Moskovic, MA,*† Alexander W. Pastuszak, MD, PhD,* Larry I. Lipshultz, MD,* and Mohit Khera, MD, MBA, MPH*

*Scott Department of Urology, Baylor College of Medicine, Houston, TX, USA; †Columbia Business School, New York, NY, USA

Specific Applications: “Adjuvant” Rx Pre-IPP

New trend? Emerging data

- Use of VEDs 2-3 months prior to IPP
- 10 min daily stretch protocol + VED → 2-3 cm cylinder length gain at the time of implant

Penile Rehabilitation Post-Prostatectomy

ED rates high despite technical improvements & RARP

- Pathophysiology: Neurogenic and vasculogenic
- VED: Improved flow; ↓ fibrosis & VOD
- ↑ PSV; ↑ corporal oxygenation
- Not dependent on intact nerves for efficacy

Burnett et al., J Urol. 2007; 178: 597-601
Penile Rehabilitation
Post-Prostatectomy

- ~30% discontinue PDE5-I Rx < 2 mo post-op
  - F/U of 77 men who had NSRAP and enrolled in rehab protocol
- An additional ~40% discontinue by 6 mo
- $ main reason for non-compliance in 65%

Lee et al., 2009. BJU Int; 105: 382-388
Post-op 15-20% penile shortening possible

- 68% - 71% of pts in 2 series experienced ↓ stretched length

- 2006: VED 5 min QOD 9 mo post-op:
  - 23% of VED group vs. 85% of non-VED group reported reduced length and girth

- Maximal penile shrinkage occurs within the first few months in the post-op period

Munding et al., Urology. 2001; 58: 567-569
Savoie et al., J Urol, 2003; 169(4). 1462-1464
Penile Rehabilitation Post-Prostatectomy

109 post prostatectomy pts randomized

- **Early VED** daily (n=74) vs. no Rx
- Spontaneous erections in 17% of VED group at 9 mo (vs. 11%)

- Early vs. late intervention results:
  - 1 mo vs. 6 mo post-op:
  - Improved with early intervention

Kohler et al., BJU Int. 2007; 100 (4): 858-862.
Possible suggested protocol:
Daily VED after catheter removal
Use constriction ring for intercourse
30 days: replace VED with PDE5-i if erection achieved
Stop after return of spontaneous erections
Penile Rehabilitation Post-Prostatectomy

Despite current phosphodiesterase-5 inhibitor treatments for ED, VED is becoming recognized again as having a primary role in early penile rehabilitation ...
Penile Rehabilitation Post-Prostatectomy

Penile rehabilitation with a vacuum erectile device in an animal model is related to an antihypoxic mechanism: blood gas evidence

Hao-Cheng Lin, Wen-Li Yang, Jun-Lan Zhang, Yu-Tian Dai \(^1\) and Run Wang

- \((↑)\) cavernous blood O2 saturation in rat model
- VED preserves penile size in rats with bilateral cavernous nerve crush injury (4 weeks therapy)

Penile Rehabilitation Post-Prostatectomy

A pilot study to determine penile oxygen saturation before and after vacuum therapy in patients with erectile dysfunction after radical prostatectomy.

Early penile hypoxia Post-RP → fibrosis → decrease in stretched penile length and ED

N=20
2 to 24 mo post op; 10x use 2 min
No constriction ring

Penile Rehabilitation Post-Prostatectomy

- Mean age = 58.2 years
- Time from surgery = 12.6 months
- Avg SHIM = 7
- VED significantly (↑) both glanular and corporal oximetry
- An initial increase of 55% was seen in corporal oxygenation with VED use.

Practical Matters

• Medicare part B covers around 80%.
• Many secondary plans will cover the balance but it’s not guaranteed.
• Med Advantage plans usually cover the same as Medicare but can vary depending upon the insurer.
• Private plans generally provide some coverage but may require use of a local retailer to maximize benefit.
Conclusion & Take Home Messages

- Following decline after PDE5-I availability, a resurgence
- Can be used as first-line Rx for ED
- May be an ideal first-line Rx in rehab
- Interim therapy before implant surgery may decrease length loss & fibrosis
- May be used in combination
- Non-invasive & cost effective
Thank You

Paraty Brazil
HSN 2014