Minimally Invasive Sex Preserving Treatment Options for LUTS/BPH

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Disclosures

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Learning Objectives

• Describe minimally invasive sex preserving treatment options
• Review recent data on urinary and sexual function outcomes
• Discuss barriers to offering new BPH therapies
The goal of this revised guideline is to provide a useful reference on the effective evidence-based surgical management of male lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH).

Panel Members

Harris E. Foster, MD; Michael J. Barry, MD; Manhar C. Gandhi, MD; Steven A. Kaplan, MD; Tobias S. Kohler, MD; Lori B. Lerner, MD; Deborah J. Lightner, MD; J. Kellogg Parsons, MD; Claus G. Roehrborn, MD; Charles Welliver, MD; Kevin T. McVary, MD.
SURGICAL THERAPY

Assessment of Prostate Size

Large Prostate

- Simple Prostatectomy
- HoLEP
- ThuLEP

Small Prostate

Average Prostate

- HoLEP
- PVP
- PUL
- ThuLEP
- TUMT
- TURP

- TURP

Size Independent Options

- HoLEP
- ThuLEP

Eligible patients who desire preservation of erectile and ejaculatory function may be offered PUL or water vapor thermal therapy as data indicate that both therapies provide a greater likelihood of preservation of sexual function.
UroLift®

Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

Claus G. Roehrborn, MD,¹ Jack Barkin, MD,² Steven N. Gange, MD,³ Neal D. Shore, MD,⁴ Jonathan L. Giddens, MD,⁵ Damien M. Bolton, MD,⁶ Barrett E. Cowan, MD,⁷ Anthony L. Cantwell, MD,⁸ Kevin T. McVary, MD,⁹ Alexis E. Te, MD,¹⁰ Shahram S. Gholami, MD,¹¹ William G. Moseley, MD,¹² Peter T. Chin, MD,¹³ William T. Dowling, MD,¹⁴ Sheldon J. Freedman, MD,¹⁵ Peter F. Ince, MD,¹⁶ K. Scott Coffield, MD,¹⁷ Sean Herron, MD,¹⁸ Prem Rashid, MD,¹⁹ Daniel B. Rukstalis, MD²⁰
Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

• Prospective, multicenter, randomized, blinded sham control trial
• 19 centers (North America and Australia)
• 206 subjects ≥ 50 yrs w/ IPSS >12, Qmax ≤ 12 mL/s, prostate 30-80 cc
• Randomized 2:1
  • PUL (140)
  • Blinded sham control (66)
  • At 3 months, subjects were unblinded and 80% of sham subjects enrolled in crossover study
Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

- Generally transient
- No new chronic ejaculatory or erectile dysfunction

**TABLE 1. Adverse events over 5 year course of study**

<table>
<thead>
<tr>
<th>Time period [months]</th>
<th>0-3</th>
<th>4-12</th>
<th>13-24</th>
<th>25-36</th>
<th>37-48</th>
<th>49-60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total available subjects</td>
<td>140</td>
<td>139</td>
<td>130</td>
<td>118</td>
<td>108</td>
<td>96</td>
</tr>
<tr>
<td>Total subject-months (SM)</td>
<td>413.6</td>
<td>1210.3</td>
<td>1463.8</td>
<td>1324.9</td>
<td>1186.6</td>
<td>1056.3</td>
</tr>
<tr>
<td>Related adverse events [total events]</td>
<td>162</td>
<td>15</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Related adverse events [subjects]</td>
<td>100</td>
<td>12</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>1</td>
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<tr>
<td>% SM with adverse event per total SM:</td>
<td></td>
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<tr>
<td>Abdominal pain</td>
<td>0.3%</td>
<td></td>
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<tr>
<td>Bladder spasm</td>
<td>0.3%</td>
<td></td>
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<tr>
<td>Chills (rigors)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.09%</td>
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<tr>
<td>Diarrhea</td>
<td>0.2%</td>
<td></td>
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<tr>
<td>Dizziness</td>
<td>0.2%</td>
<td></td>
<td></td>
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<tr>
<td>Fever (pyrexia)</td>
<td>0.06%</td>
<td></td>
<td></td>
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<tr>
<td>Vomiting</td>
<td>0.02%</td>
<td></td>
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<tr>
<td>Hypotension</td>
<td>0.04%</td>
<td></td>
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<tr>
<td>Orchitis/epididymo-orchitis</td>
<td>0.3%</td>
<td></td>
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<tr>
<td>Painful erection</td>
<td>0.2%</td>
<td></td>
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<tr>
<td>Urinary retention</td>
<td>0.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Urethral stenosis (stricture)</td>
<td>&lt; 0.01%</td>
<td>&lt; 0.01%</td>
<td></td>
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<tr>
<td>Prostatitis</td>
<td>0.4%</td>
<td></td>
<td>0.06%</td>
<td></td>
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<tr>
<td>Urinary tract infection</td>
<td>0.1%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td></td>
<td></td>
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<tr>
<td>Pelvic pain</td>
<td>6%</td>
<td>1%</td>
<td></td>
<td></td>
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<tr>
<td>Hematuria</td>
<td>4%</td>
<td>0.2%</td>
<td>0.3%</td>
<td>0.07%</td>
<td>0.07%</td>
<td></td>
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<tr>
<td>Dysuria</td>
<td>9%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td></td>
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<tr>
<td>Urinary urge incontinence</td>
<td>3%</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>4%</td>
<td>3%</td>
<td>5%</td>
<td>4%</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>
Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

Figure 2. Intent to Treat outcomes for PUL and Sham control for a) International Prostate Symptom Score (IPSS); b) Quality of Life (QOL); c) BPH Impact Index (BPHII); d) peak urinary flow rate (Qmax).
Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

- Summary
  - LUTs and QOL significantly improved by 2 weeks
  - 104/140 (74.3%) PUL subjects with FU at 5 yr
  - Durable through 5 yrs
  - Surgical retreatment 13.6% over 5 yrs (18 w/ IPSS≥20, 1 w/ 19)
    - 6 (4.3%) additional PUL implants
    - 13 (9.3%) TURP or laser ablation
      - No adverse effects from implants
  - Medical retreatment 10.7% at 5 yrs (alpha blocker or 5-ARI)
AUA Guidelines

• Consider PUL when prostate <80g without obstructive middle lobe
• Inform patients:
  • Symptom reduction and flow rate improvement is less significant compared to TURP
  • Evidence of efficacy and retreatment rates are poorly defined
Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Woo HH¹, Bolton DM, Laborde E, Jack G, Chin PT, Rashid P, Thavaseelan J, McVary KT.

- 64 men in Australia (average 66.9 yr)
- Primary inclusion criteria: IPSS>13, Qmax 5-12 mL/s, PSA<10 ng/mL
  - No inclusion criteria for sexual function
- Baseline IPSS 22.9 ± 5.4
- Baseline SHIM 11.7 ± 8.6 (N = 58)
- Baseline MSHQ-EjD 9.0 ± 3.7 (N = 46)
- Evaluated at 6 wks, 3, 6, and 12 months post op
  - No degradation in sexual function, no reported RE
Prospective, randomized, controlled, non-blinded (80 patients)

Significant improvements in IPSS, IPSS quality of life, BPH Impact Index (BPHII), and $Q_{\text{max}}$ in both arms
- Change in IPSS and $Q_{\text{max}}$ superior in TURP
- Recovery, ejaculatory function preservation, performance on composite BPH6 index superior in PUL

No AEs related to sexual function w/ PUL (w/ TURP, ED in 9% and RE in 20%)
**Medical Necessity Criteria:**

<table>
<thead>
<tr>
<th>Medical Necessity Criteria</th>
<th>Tricare</th>
<th>United Healthcare (UHC)</th>
<th>Wellmark BCBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate size ≤ 80g</td>
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<tr>
<td>Prostate size confirmed by TRUS / Pelvic US</td>
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<tr>
<td>Absence of obstructive median lobe</td>
<td></td>
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<tr>
<td>Age requirement</td>
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<tr>
<td>AUASI threshold required</td>
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<tr>
<td>PVR &gt; 50cc on &lt; 350cc</td>
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<tr>
<td>PSA in men up to 60 yrs</td>
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<tr>
<td>PSA in men over 60 yrs</td>
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<tr>
<td>If PCa Hx/Dx, either not resection candidate or PSA &lt; 1.0 ng/mL</td>
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<tr>
<td>Uroflow (Qmax)</td>
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<tr>
<td>Absence of gross hematuria or urinary incontinence</td>
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<tr>
<td>Not in urinary retention</td>
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<tr>
<td>No active UTI</td>
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<tr>
<td>No bacterial prostatitis</td>
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<tr>
<td>No known allergy to nickel</td>
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<tr>
<td>Normal renal function</td>
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<tr>
<td>Failed Rx and/or why Rx not suitable</td>
<td></td>
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<tr>
<td>Why other surgery not suitable</td>
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<tr>
<td>Normal bladder neck</td>
<td></td>
<td></td>
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<tr>
<td>No Dx of prostate cancer</td>
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<tr>
<td>Not a candidate for surgery using general anesthesia like TURP</td>
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</table>

*NONE*
Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study

Kevin T. McVary, Tyson Rogers, and Claus G. Roehrborn
Rezūm: 4 year follow up

• 15 centers
• ≥ 50 yr w/ IPSS ≥ 13, Qmax ≤ 15 mL/s, prostate 30-80 cc, PVR <250 mL
• Randomized 2:1 (Rezūm: Control)
  • 90 participants at 48 mo
  • 53 crossover (30 participants at 36 mo)
Rezūm: 4 year follow up

Adverse events

- Dysuria (16.9%)
- Hematuria (11.8%)
- Frequency and urgency (5.9%)
- Acute urinary retention (3.7%)
- Suspected urinary tract infection (3.7%)

Resolution within 3 wks

No de novo ED (2 pts w/ decreased ejac vol)
Rezūm: 4 year follow up

Summary

- IPSS improvement vs control at 3 mo
- Similar in those with treated median lobe
- LUTS significantly improved within ≤3 mo
- Durable throughout 4 and 3 yrs in tx and crossover pts, respectively
- *Surgical retreatment 4.4% over 4 yrs (open, plasma-button vaporization, Rezūm)*
- *Medical retreatment 5.2% (alpha blockers) over 4 yrs*
Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should be counseled regarding efficacy and retreatment rates.
Rezūm

• CPT code
• Reimbursement
• Technology
THANK YOU

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