Radical Prostatectomy
Pathologic Features
PSA Era

• Detecting Curable Cancers
  – ⇩ Distant Metastasis
  – ⇩ Lymph Node Metastasis
  – ⇩ Seminal Vesicle Involvement
  – ↑ Organ Confined Cancer

• Majority (> 75%) Clinically Significant
Radical Prostatectomy versus Watchful Waiting in Early Prostate Cancer

Anna Bill-Axelson, M.D., Lars Holmberg, M.D., Ph.D., Mirja Ruutu, M.D., Ph.D., Michael Häggman, M.D., Ph.D., Swen-Olof Andersson, M.D., Ph.D., Stefan Bratell, M.D., Ph.D., Anders Spångberg, M.D., Ph.D., Christer Busch, M.D., Ph.D., Stig Nordling, M.D., Ph.D., Hans Garmo, Ph.D., Juni Palmgren, Ph.D., Hans-Olov Adami, M.D., Ph.D., Bo Johan Norlén, M.D., Ph.D., Jan-Erik Johansson, M.D., Ph.D., for the Scandinavian Prostate Cancer Group Study No. 4

- **Patients**
  - 695, <75 years, 10 year life expectancy
  - >50% symptoms

- **Clinical Stage**
  - T₁-T₂
  - Negative Bone Scan

- **Serum Prostate Specific Antigen**
  - <50 ng/ml
  - Median, 12.3 – 13.5 ng/ml

- **Endpoints Estimate @ 10 Years**
  - Disease specific and overall mortality
  - Metastases, local progression

- **Mean Follow-Up**
  - Prostatectomy, 85. years
  - Watchful waiting, 8.8 years

## Radical Prostatectomy versus Watchful Waiting
### Results @ 10 Years

<table>
<thead>
<tr>
<th>Condition</th>
<th>Radical Prostatectomy (%)</th>
<th>Watchful Waiting (%)</th>
<th>Percent Relative Reduction</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Specific Mortality</td>
<td>9.6</td>
<td>14.9</td>
<td>44</td>
<td>0.01</td>
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<tr>
<td>Distant Metastasis</td>
<td>15.2</td>
<td>25.4</td>
<td>40</td>
<td>0.004</td>
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<tr>
<td>Local Progression</td>
<td>19.2</td>
<td>44.2</td>
<td>67</td>
<td>&lt;0.001</td>
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<tr>
<td>Overall Mortality</td>
<td>27</td>
<td>32</td>
<td>26</td>
<td>0.04</td>
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</table>

Prostate Cancer 2007

Increasing Favorable Tumor Detection!

• New Biopsy Strategies

• Lower Prostate Specific Antigen Cut-Offs
Prostate Biopsy
TRUS Guided
Multisite Biopsy Strategy\(^{(1-3)}\)

Sextant pattern - **high false negative rate**

- 11 core multisite BX increases cancer detection 33% by adding
  - Anterior horns
  - Transition zone
  - Midline

- 10-12 core sextant & laterally directed BX most common currently

\(^{(1)}\) Babaian et al., J Urol 163: 152, 2000
\(^{(2)}\) Chen et al., Urology 53: 951, 1999
\(^{(3)}\) Singh et al., J Urol 171: 1089, 2004
# Prostate Cancer Incidence

## Serum PSA Levels ≤ 4ng/mL

<table>
<thead>
<tr>
<th>Study</th>
<th># Men</th>
<th>% Biopsied</th>
<th>Serum PSA Interval ng/ml</th>
<th>Cancer Incidence %</th>
<th>Organ Confined (%)</th>
<th>Clinically Significant Cancer (%)</th>
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<tbody>
<tr>
<td>Catalona(1)</td>
<td>914</td>
<td>36</td>
<td>2.6-4.0</td>
<td>22</td>
<td>81</td>
<td>83</td>
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<tr>
<td>Babaian (2)</td>
<td>268</td>
<td>56</td>
<td>2.5-4.0</td>
<td>24</td>
<td>86</td>
<td>71</td>
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<td>Thompson (3)</td>
<td>193</td>
<td>83</td>
<td>3.1-4.0</td>
<td>27</td>
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<td>---</td>
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<tr>
<td></td>
<td>482</td>
<td>83</td>
<td>2.1-3.0</td>
<td>24</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>998</td>
<td>83</td>
<td>1.1-2.0</td>
<td>17</td>
<td>---</td>
<td>---</td>
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<tr>
<td></td>
<td>791</td>
<td>83</td>
<td>0.6-1.0</td>
<td>10</td>
<td>---</td>
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<tr>
<td></td>
<td>486</td>
<td>≤ 0.5</td>
<td>6.6</td>
<td>6.6</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

(1) JAMA 277: 1452, 1997 – biopsy technique not specified  
(2) J Urol 165: 2001  
Prostate Cancer Dilemmas: 2007

• Do all “favorable risk” tumors need immediate treatment?
  – Active surveillance + delayed intervention

• Are “minimally invasive” surgical alternatives to open retropubic prostatectomy effective?
  – Cryosurgical ablation of prostate
  – High intensity focused ultrasound (HIFU)
  – Robotic assisted laparoscopic prostatectomy (RALP)

(1) T1c-T2a and Gleason Score ≤ 6, and serum PSA level < 10 ng/ml
Active Surveillance
Favorable Risk Prostate Cancer (1)

Rationale

• Lead Time (2)
  – “PSA screening” results in detection of cancer 10 years prior to “clinical detection”
  – Over-diagnosis over-treatment

• Favorable Natural History (3)
  – Gleason ≤ 6 prostate cancer managed by watchful waiting
    • 80-90% cancer specific survival

(1)T1c – T2a & Gleason ≤ 6 & Serum PSA < 10 ng/ml
(3) Albertsen et al. JAMA 293:2095, 2005
Active Surveillance Favorable Risk Prostate Cancer “Fears”

• Undersampling
  – Presence of “high grade” cancer not always predicted

• Imprecise Prediction of Disease Biology (1)
  – Gleason score 6 cancers exhibit > 2 ng/ml/yr increase in 25%

• Inability to Rescue
  – Surveillance compromises ability for later cure if required

Active Surveillance
Favorable Risk Prostate Cancer
Toronto Experience (1)

• Patients
  – N = 299
• Characteristics
  – PSA < 10 ng/ml, T1c – T2a
  – Gleason score ≤ 6
  – 20% cohort – intermediate risk features (2)
• Intervention
  – PSA DT < 2 years (3)
  – Gleason score ≥ 8 on rebiopsy (3)
• Follow-up
  – 64 months
    • 66% remain on surveillance
    • 34% OFF
      – 15% biochemical progression
      – 3% clinical progression
      – 4% histologic progression
      – 12% patient preference

(1) Klotz: J Clin Oncol 23:8165, 2005
(2) PSA < 15, Gleason score, 3+4=7
(3) Later changed to PSA DT < 3 years and Gleason 4+3=7
Active Surveillance
Favorable Risk Prostate Cancer
Toronto Experience: Results

• Prostate Cancer Death
  – 2/299

• Median PSA DT
  – 7 years

• Radical Prostatectomy Data
  – 24 men PSA DT < 2 years
    • 10/24 (42%) = pT2
    • 14/24 (58%) > pT3

(1) Klotz: J Clin Oncol 23:8165, 2005
Active Surveillance
Favorable Risk Prostate Cancer
Hopkins Experience

• **Selection Criteria**
  - T1C, PSA density \( \leq 0.15 \text{ ng/ml/cm}^3 \)
  - Biopsy Gleason score \( \leq 6 \), \( \leq 2 \) positive cores, \( \leq 50\% \) core involved

• **Patients**
  - \( N = 320 \) men from 1995-2005
  - 1\% of newly diagnosed prostate cancer enrolled

• **Intervention**
  - 98 total (31\%)
  - 38 radical prostatectomy (RP)

• **Comparison Study – Pathologic Features**
  - Delayed RP, \( N = 38 \)
    - Median 26.5 months (12-73)
  - Immediate RP, \( N = 150 \)
    - Median 3 months (1-9)

Active Surveillance
Favorable Risk Prostate Cancer
Hopkins Experience: Immediate versus Delayed Prostatectomy (1)

- Incidence Noncurable Prostate Cancer (2)
  - Delayed RP
    - 9/38 (23%)
  - Immediate RP
    - 24/150 (16%)
  - Relative Risk
    - Unadjusted = 1.48 (0.75 – 2.92) p = 0.266
    - Adjusted (3) = 1.08 (0.55 – 2.12) p = 0.819

(2) < 75% chance BDF @ 10 years (pT2 + Gleason > 4+3=7 or positive margin, pT3A & Gleason = 7 or positive margin, or > pT3A or positive lymph nodes
(3) Age, PSA density
Active Surveillance
Favorable Risk Prostate Cancer

- Rational, Increased Acceptance
- Optimal Strategy
  - In evolution
    - Biomarkers urgently needed!
    - Clinical trial should be supported
COLD KILLS
Treatment Planning

- Individual patient anatomy can be entered into a computer-based treatment planning system.

- This computer system helps optimize positioning of the cryotherapy probes and thermocouple positions.
Placement of Cryoprobes and Thermocouples

- Cryoprobes and thermocouples are placed transperineally through a grid or by manual guidance.
- They are guided into place with ultrasound.
Ice Formation and Monitoring
Sagittal Image of Posterior Ice Start
Probes Placed before Freezing
Freeze Started in the Anterior
Sagital Image of Posterior Ice Start
Ice Stopped at Denonvillier's Fascia
## Efficacy of Primary Cryotherapy

<table>
<thead>
<tr>
<th>Ref.</th>
<th>N</th>
<th>Crygen</th>
<th>Median F/U (Mos.)</th>
<th>Nadir PSA undetectable (%)</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>When</th>
<th>Definition</th>
<th>Neg Biopsies (%)</th>
<th>ADT (%)</th>
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<tbody>
<tr>
<td>Prepelica, 2005</td>
<td>65</td>
<td>A</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
<td>83%</td>
<td>3 Yrs</td>
<td>ASTRO</td>
<td>7/8 (88)</td>
<td>68</td>
</tr>
<tr>
<td>Han, 2003</td>
<td>122</td>
<td>A</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td>75%</td>
<td>1 Yr</td>
<td>PSA &gt;0.5 ng/ml</td>
<td></td>
<td>37</td>
</tr>
<tr>
<td>Donnelly, 2002</td>
<td>76</td>
<td>N</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td>75%</td>
<td>50 Mos</td>
<td>PSA &gt;1.0 ng/ml</td>
<td>63/73 (86)</td>
<td>34</td>
</tr>
<tr>
<td>Bahn, 2002</td>
<td>590</td>
<td>A/N</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
<td>92%</td>
<td>7 Yrs</td>
<td>ASTRO</td>
<td>514/590 (87)</td>
<td>91</td>
</tr>
<tr>
<td>Long, 2001</td>
<td>975</td>
<td>A/N</td>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td>92%</td>
<td>5 Yrs</td>
<td>PSA &gt;1.0 ng/ml</td>
<td></td>
<td>33</td>
</tr>
<tr>
<td>De La Taille, 2000</td>
<td>35</td>
<td>A</td>
<td>8.3</td>
<td>22 (63)</td>
<td></td>
<td></td>
<td>70%</td>
<td>9 Mos</td>
<td>PSA increase 0.2 above nadir</td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>Koppie, 1999</td>
<td>176</td>
<td>N</td>
<td>31</td>
<td>88 (49)</td>
<td></td>
<td></td>
<td>56%</td>
<td>3 Yrs</td>
<td>Nadir &gt;0.5 or PSA increase of 0.2</td>
<td>103/167 (61)</td>
<td>28</td>
</tr>
</tbody>
</table>
## Primary Cryotherapy Complications (%)

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Erectile Dysfunction</th>
<th>Fistula</th>
<th>Incontinence</th>
<th>Sloughing / TURP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Han, 2003</td>
<td>122</td>
<td>87</td>
<td>0</td>
<td>4.3</td>
<td>5.8</td>
</tr>
<tr>
<td>Ellis, 2006</td>
<td>75</td>
<td>82</td>
<td>0</td>
<td>5.5</td>
<td>6.7</td>
</tr>
<tr>
<td>Long, 2001</td>
<td>975</td>
<td>93</td>
<td>0.5</td>
<td>7.5</td>
<td>13</td>
</tr>
<tr>
<td>Bahn, 2001</td>
<td>590</td>
<td>95</td>
<td>0.1</td>
<td>4.3</td>
<td>5.5</td>
</tr>
</tbody>
</table>
Nerve-Sparing Prostate Cryoablation

Goal: Treat prostate tissue while warming one or both neurovascular bundles to improve erectile function.
Focal Prostate Cryoablation

Goal: Completely treat the side of the prostate with the cancer, avoiding any ice ball formation on the contralateral side in order to improve erectile function.
# Focal Cryotherapy – Early Results

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Follow-up (months)</th>
<th>PSA Results</th>
<th>Positive Post-Treatment Biopsy (%)</th>
<th>Potency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onik, 2002</td>
<td>9</td>
<td>36</td>
<td>Stable</td>
<td>0/6 (0%)</td>
<td>7/9 (77%)</td>
</tr>
<tr>
<td>Bahn, 2006</td>
<td>31</td>
<td>70</td>
<td>26/28 (93%) (by Astro)</td>
<td>1/25 (4%)</td>
<td>24/27 (89%) With or without drugs</td>
</tr>
<tr>
<td>Lambert, 2007</td>
<td>25</td>
<td>28</td>
<td>21/25 (84%) (&gt;50% nadir Reduction)</td>
<td>3/7 (43%)</td>
<td>17/24 (71%) With or without drugs</td>
</tr>
</tbody>
</table>
Prostate Cryoablation Versus External Beam Radiotherapy
A Randomized Controlled Trial (1)

- **Patients**
  - N = 244
  - T1-3, Nx M0
  - PSA < 20 ng/ml

- **Treatment**
  - Neoadjuvant Androgen Deprivation
    - Cryoablation
    - External beam radiotherapy (68-73 GY)

- **Results @ 3 years**
  - Biochemical Failure (2)
    - Cryoablation = 25 (20%)
    - External Beam = 35 (26%)
  - Positive Prostate Biopsy
    - Cryoablation = 6.6%
    - External Beam = 26.3%

---

(2) Astro definition: Nadir + 2 ng/ml PSA
Cryotherapy - Conclusions

- Minimally invasive
  - Outpatient
  - Rapid recovery
- Cryotherapy is an acceptable alternative to EBRT
  - Equivalent PSA outcomes
  - Fewer positive biopsies
    (based on a randomized trial)
- High potency rates with focal cryo (approximately 70-90%)
  - Longer follow-up needed!
- Most appropriate in older patients as an alternative to radiation therapy
Laparoscopic Prostatectomy

- ↓ Blood Loss
- ↓ Transfusion
- ↓ Bladder Neck Contractures
- ↓ Pain Medication Requirement
- ↓ Time to Return to Normal Activity

Robotic Assisted Laparoscopic Prostatectomy
Robotic Assisted Laparoscopic Prostatectomy
Robotic, Laparoscopic, Open Radical Prostatectomy: Perioperative Comparisons (1)

<table>
<thead>
<tr>
<th>Method</th>
<th>No. Patients</th>
<th>No. Series</th>
<th>Years</th>
<th>OR Time</th>
<th>Mean EBL (ml)</th>
<th>Blood Transfusion (%)</th>
<th>Conversion Rate (%)</th>
<th>Catheter Time (Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic</td>
<td>373</td>
<td>10</td>
<td>2001-2004</td>
<td>254</td>
<td>231</td>
<td>3.9</td>
<td>1.1</td>
<td>8.1</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>1106</td>
<td>5</td>
<td>2001-2002</td>
<td>225</td>
<td>505</td>
<td>8.4</td>
<td>1.4</td>
<td>6.1</td>
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<tr>
<td>Open</td>
<td>3200</td>
<td>3</td>
<td>1994-2001</td>
<td>182</td>
<td>727</td>
<td>24</td>
<td>—</td>
<td>7-21</td>
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<table>
<thead>
<tr>
<th>Method</th>
<th>No. Patients</th>
<th>No. Series</th>
<th>Overall Complications</th>
<th>Minor Complications</th>
<th>Major Complications</th>
<th>Mortality</th>
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<tbody>
<tr>
<td>Robotic</td>
<td>373</td>
<td>11</td>
<td>8.3</td>
<td>4.6</td>
<td>3.8</td>
<td>0</td>
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<td>Laparoscopic</td>
<td>1006</td>
<td>4</td>
<td>16.8</td>
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<td>4.9</td>
<td>0</td>
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<tr>
<td>Open</td>
<td>6677</td>
<td>4</td>
<td>10.3</td>
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<td>4.0</td>
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</table>

Robotic, Laparoscopic, Open Radical Prostatectomy: Pathological Comparisons (1)

<table>
<thead>
<tr>
<th>Method</th>
<th>No. Patients</th>
<th>No. Series</th>
<th>Years</th>
<th>pT₂</th>
<th>pT₃</th>
<th>Margin+</th>
<th>pT₂+</th>
<th>pT₃+</th>
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<tr>
<td>Robotic</td>
<td>373</td>
<td>11</td>
<td>2001-2005</td>
<td>77.5</td>
<td>21.6</td>
<td>15</td>
<td>8.5</td>
<td>57.3</td>
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<td>Laparoscopic</td>
<td>1439</td>
<td>4</td>
<td>2001-2002</td>
<td>72.4</td>
<td>26.5</td>
<td>19.9</td>
<td>13.8</td>
<td>31.3</td>
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<tr>
<td>Open</td>
<td>22,164</td>
<td>5</td>
<td>2000-2004</td>
<td>64</td>
<td>32.2</td>
<td>24.1</td>
<td>17.5</td>
<td>42.7</td>
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</table>

## Robotic, Laparoscopic, Open Radical Prostatectomy: Continence Rates

<table>
<thead>
<tr>
<th>Method</th>
<th>No. Patients</th>
<th>Age</th>
<th>1</th>
<th>3</th>
<th>6</th>
<th>12</th>
<th>Eval Method</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Robotic</td>
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<td></td>
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</tr>
<tr>
<td>Bentas</td>
<td>38</td>
<td>61.3</td>
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<td></td>
<td>84</td>
<td></td>
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<td>0-1 pad/24 hr</td>
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<tr>
<td>Ahlering</td>
<td>45</td>
<td>61.4</td>
<td>63</td>
<td>81</td>
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<td>76</td>
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<tr>
<td>Menon</td>
<td>200</td>
<td>59.9</td>
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<td></td>
<td>96</td>
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<td>Questionnaire</td>
<td>0-1 pad/24 hr</td>
</tr>
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<td>Tewari</td>
<td>100</td>
<td>65</td>
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<td></td>
<td></td>
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<tr>
<td>Laparoscopic</td>
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<td>Guillonneau</td>
<td>60</td>
<td>64</td>
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<td></td>
<td>73</td>
<td></td>
<td>Questionnaire</td>
<td>0 pads</td>
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<tr>
<td>Rassweiler</td>
<td>179</td>
<td>64</td>
<td>36</td>
<td>54</td>
<td>74</td>
<td>97</td>
<td>Questionnaire</td>
<td>0 pads</td>
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<td>Turk</td>
<td>125</td>
<td>59.9</td>
<td></td>
<td>75</td>
<td>86</td>
<td>92</td>
<td>Patient Interview</td>
<td>0-1 pad</td>
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<td>Open</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Kundu/Catalona</td>
<td>2737</td>
<td>61±7.4</td>
<td></td>
<td></td>
<td></td>
<td>93</td>
<td>(2) Questionnaire</td>
<td>0 Pads</td>
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<tr>
<td>Walsh</td>
<td>64</td>
<td>57</td>
<td>54</td>
<td>80</td>
<td>93</td>
<td></td>
<td>Questionnaire</td>
<td>0 Pads</td>
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<tr>
<td>PCOS</td>
<td>1291</td>
<td>62.9</td>
<td></td>
<td></td>
<td>38.6</td>
<td>60.5</td>
<td>Questionnaire</td>
<td>0 Pads</td>
</tr>
</tbody>
</table>

(2) Data at ≥ 18 mos.
# Robotic, Laparoscopic, Open Radical Prostatectomy: Postoperative Potency

<table>
<thead>
<tr>
<th>Method</th>
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Robotic Prostatectomy
Conclusions

• Safe, Effective Form of Prostate Removal
  – Similar perioperative complications
  – ↓ blood loss
  – Comparable rates negative surgical margins among low-intermediate risk patients
    • Role in high risk/locally advanced remains to be defined
  – Postoperative urinary/sexual function
    • Results encouraging
      – May lead to earlier return of urinary/sexual function

• Future Role
  – Here to stay!
    • Prospective comparison studies
    • Cost must decrease
    • Facilitate training future surgeons