ROBOTIC RADICAL CYSTECTOMY FOR BLADDER CANCER

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Bladder Cancer:
- 70,980 cases per year in U.S.
  - Rising incidence – 40% since 1975
- 14,330 deaths per year
  - Stable / slight decline
- 600,000 survivors in the U.S.

Bladder Cancer:
- 70-75% are non-muscle invasive (Ta, Tis, T1)
  - 70% recur
  - 25% progress to higher stage or grade
- 20-25% are muscle invasive (T2, T3, T4)
- 5% are metastatic

Bladder Cancer: Staging (AJCC 1997)
- Ta (non-invasive, papillary)
- Tis (CIS)
- T1 (invades lamina propria)
- T2 (invades muscle)
- T3 (invades perivesical tissue)
- T4 (invades adjacent organs)
  - T4a = prostate, uterus, vagina
  - T4b = pelvic, abdominal wall

Management of Bladder Cancer
- "Caged" Tiger
- "Uncaged" Tiger
- Bladder Preservation
- Cystectomy

Indications for radical cystectomy
- Muscle-invasive bladder cancer
- Recurrent high-risk non-invasive cancer
  - T1 tumors unresponsive to BCG therapy
  - CIS refractory to BCG therapy
- Palliation
  - pain, bleeding, or voiding dysfunction
Radical Cystectomy

- Provides best chance at local control / survival for invasive disease
- Historically -- concerns regarding the high morbidity of surgery

Recent Improvements

- Improved pelvic surgical experience
  - Radical prostatectomy volumes
- Peri-operative care - Clinical Care Pathways
  - e.g. non-narcotic analgesics
- Technology
  - Staplers, hemostatic devices (Ligasure, Harmonic scalpel)
  - Potential role of laparoscopy / robotics

Robotic Cystectomy Session

- Review of principles and outcomes
- Video description
  - Step-by-step
  - Edited complete cystectomy
  - Robotic PLND
  - Female cystectomy
  - Intracorporeal diversion
  - (modifications – partial cystectomy, prostate-sparing)
- Complications and cystectomy
- Getting started

OUTCOMES WITH ROBOTIC RADICAL CYSTECTOMY FOR BLADDER CANCER

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Robotic Cystectomy

- Has emerged from growing experience with robotic assisted prostatectomy
- May offer viable alternative to open radical cystectomy in select patients

Robotic-assisted Radical Cystectomy

- Potential benefits
  - Reduced ebl
  - Decreased incision / pain
  - Less fluid imbalances
  - Decreased bowel manipulation
- Potential Concerns
  - Maintain oncological principles
    - Margins, bladder entry, tumor seeding, LN’s
  - Per-operative results
  - Prolonged OR times, complications
  - Learning curve
  - Costs
Principles

• Indications for cystectomy
• Peri-operative management
  – Use of neoadjuvant / adjuvant chemotherapy
  – Peri-operative care – clinical care pathways
• Extirpative procedure
  – Completeness of resection
  – LN dissection – templates/extent
• Urinary diversion

Oncologic outcomes

Priorities

• Oncologic outcomes
  – RFS and DSS (2-yr and 5-yr)
  – Surrogates
    • Soft tissue margins
    • LN yield
• Morbidity
  – Peri-operative outcomes
    • EBL, Pain, Bowel recovery, Discharge, Complications
    • Functional recovery
    • Return to activities, urinary function, sexual function
• Other
  – Learning curve
  – Costs

Standardization for open radical cystectomy

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases /year</td>
<td>At least 10/year to maintain proficiency</td>
</tr>
<tr>
<td>Overall Margin Status</td>
<td>Less than 10%</td>
</tr>
<tr>
<td>Margins in Bulky (T3-4) Disease</td>
<td>Less than 15%</td>
</tr>
<tr>
<td>Standard PLND</td>
<td>At least 80% cases</td>
</tr>
<tr>
<td>Lymph Node Yield</td>
<td>At least 10-14</td>
</tr>
</tbody>
</table>


Priorities

• Oncologic outcomes
  – RFS and DSS (2-yr and 5-yr)
  – Surrogates
    • Soft tissue margins
    • LN yield
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“Not so long ago at all, cystectomy was performed using a traditional open surgical procedure; and therefore usually involved notable tissue and nerve damage, significant blood loss and carried a greater risk of post-operative infections and complications. By comparison, the robotic-assisted laparoscopic cystectomy may seem a bit like a kind of state-of-the-art miracle.”

“Robotic-assisted cystectomy also offers patients a cancer removal rate that is 14% higher.”

Unit Onc (2009)
Rate confidence RALC can achieve comparable negative margins to open

Davis J et al. SUO Survey 2008

Peer-reviewed literature

- RCT (1)
- Case series (9)
- Multi-institutional (n=4) analysis
- IRCC (International Robot-Assisted Cystectomy Consortium)

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Survival

- Castle et al (2009)
  - N = 80; mean FU 25 months
  - 31 pts followed >=12 months
  - DSS = 87% at 12 months; 71% at 36 months
- Dasgupta (2009)
  - N = 20; mean FU 23 months
  - RFS = 90%
- Pruthi et al (2010)
  - N = 100
  - Mean FU 21 months (5-44 mos)
  - RFS = 85%
Medium-term Oncologic Outcomes

- From a combined series of 271 patients (UNC + Mayo-Scottsdale)
  - N = 139 with >= 2 years FU
    - <= pT2 = 44%
    - pT3-T4 = 27%
    - N+ = 29%
- Mean FU = 36 months
  - RFS = 71%
  - DSS = 80%
  - OS = 68%

Comparable to reports in open series

LN+ Patients

- Combined Series (n=271)
  - N = 50 with N+ and >= 1 year FU
    - pT2 = 34%
    - pT3-4 = 66%
    - 80% pts received peri-op chemo
    - Mean LNs = 18
    - Mean positive LN = 3.1
    - Mean LND = 18%
- Mean FU = 29 months
  - RFS = 42%
  - DSS = 58%

Comparable to reports in open series

Priorities

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Positive Margins

- Features of Tumor
  - Stage, size, extent
- Quality of Surgery
  - Procedure, ability, experience

Positive Margins

- Features of Tumor
  - Stage, size, extent
- Quality of Surgery
  - Procedure, ability, experience

Does the robotic approach increase positive margin rates?

Implications

- Increased local recurrence
- Decreased RFS 26-29% (vs. 68-76%)
- Decreased DSS (HR 2.0 - 2.6)
- Association with stage (gender, histology, LVI)
- Independent predictor of recurrence / DSS
- Sites - Posterior / lateral (53-78%)

Hadjizacharia (2008)
Dotan (2007)
**Positive Soft Tissue Margin Rates**

- Open: 1.1 - 14.0%
- Robotic: 0.0 – 14.0%

Hadjizacharia (2008)
Dotan (2007)
Herr (SWOG) (2004)
Brendler (1990)
Wang (2008)
Abraham (2007)
Guru (2007)
Pruthi (2008)

**Current Literature**

<table>
<thead>
<tr>
<th>Author</th>
<th>No.</th>
<th>Margin Positive</th>
<th>Overall</th>
<th>&lt;= T2</th>
<th>&gt;T2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruthi (2007)</td>
<td>20</td>
<td>0%</td>
<td>0/20</td>
<td>0/0</td>
<td></td>
</tr>
<tr>
<td>Wang (2007)</td>
<td>33</td>
<td>6%</td>
<td>0/17</td>
<td>2/16</td>
<td></td>
</tr>
<tr>
<td>Murphy (2008)</td>
<td>23</td>
<td>0%</td>
<td>0/19</td>
<td>0/4</td>
<td></td>
</tr>
<tr>
<td>Guru (2008)</td>
<td>125</td>
<td>0%</td>
<td>0/55</td>
<td>10/70</td>
<td></td>
</tr>
<tr>
<td>Castle (2009)</td>
<td>100</td>
<td>3%</td>
<td>0/51</td>
<td>3/49</td>
<td></td>
</tr>
<tr>
<td>Pruthi (2010)</td>
<td>100</td>
<td>0%</td>
<td>0/67</td>
<td>0/33</td>
<td></td>
</tr>
</tbody>
</table>

**IRCC: Positive Margins**

- Overall positive margin rate = 6.8%

<table>
<thead>
<tr>
<th>Tumor stage</th>
<th>Positive margins</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0-T1</td>
<td>5/327</td>
<td>1.5%</td>
</tr>
<tr>
<td>T3-T4</td>
<td>3/181</td>
<td>17%</td>
</tr>
</tbody>
</table>

- Collaborative Group (open) (n=1,091) = 6.5%
- Recent multicenter (open) (n=4,410) = 6.3%

Herr (2004)
Novara (2010)

**Priorities**

- **Oncologic outcomes**
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    - EBL, Pain, Bowel recovery, Discharge, Complications
  - Functional recovery
    - Return to activities, urinary function, sexual function
- **Morbidity**
- **Other**
  - Learning curve
  - Costs
- **Lymphadenectomy**
  - Pelvic LND is standard adjunct to cystectomy for UC
  - Definitions of PLND
    - Limited
    - Standard
    - Extended
  - Variables affecting counts
    - Packets
    - Pathology analysis
    - Patient anatomy / inherent node counts
    - Extent of dissection / templates

**Procedure**

- Posterior
- Lateral

**Lymphadenectomy**
Lymphadenectomy

- Pelvic LND is standard adjunct to cystectomy for UC
- Definitions of PLND
  - Limited
  - Standard
  - Extended
- Variables affecting counts
  - Packets
  - Pathology analysis
  - Patient anatomy / inherent node counts
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Can robotics replicate open standards – templates / counts?

Comparison to Open

- Endometrial Cancer
  - Matched for age, stage, BMI
  -Rad Hysterectomy + LND (pelvic + para-aortic)
  -Mean LN’s

<table>
<thead>
<tr>
<th>Series</th>
<th>LN Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>Castle (n=80)</td>
<td>21 (7-35)</td>
</tr>
<tr>
<td>Guru (n=127)</td>
<td>27 (6-68)</td>
</tr>
<tr>
<td>Omstein (n=35)</td>
<td>22 (14-36)</td>
</tr>
<tr>
<td>Pruthi (n=100)</td>
<td>19 (8-37)</td>
</tr>
<tr>
<td>Davis (n=10)</td>
<td>38 (19-63)</td>
</tr>
<tr>
<td>IRCC (n=529)</td>
<td>18 (0-68)</td>
</tr>
<tr>
<td>Multi-inst (n=227)</td>
<td>18 (3-52)</td>
</tr>
<tr>
<td>Herr et al (n=1091)</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Comparison to Open

ROBOT PLND FOR BLADDER CANCER WITH 2ND LOOK OPEN EVALUATION

- Mean % Nodal Yields
  - O robot = 73%
  - S robot = 96%

-80 Zones from 10 cases, 2nd look results:
  - No tissue submitted: 57 (71%)
  - Tissue submitted, no nodes: 10 (13%)
  - Tissue submitted, nodes present: 13 (16%)

- No positive LN captured by 2nd look open

LN Yield from published series

Sample Size Calculation

- Alpha = 0.05
- Beta = 0.20
- Expected Variance = 0.0625
- LN standard deviation in prior studies = 5
- Acceptable difference of 4 lymph nodes
- Sample size of 20 required in each group
- Target accrual of 40 patients
• Demonstrated non-inferiority of LN yield
  - 19 vs 18 LN

<table>
<thead>
<tr>
<th>Pathologic stage</th>
<th>Robotic (n=21)</th>
<th>Open (n=20)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2N0 or lower</td>
<td>14</td>
<td>8</td>
<td>0.2248</td>
</tr>
<tr>
<td>T2N1 or T3N0</td>
<td>3</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>T4N+</td>
<td>4</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>Positive margins</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
</tbody>
</table>

Table 3 - Pathologic outcomes

• Mean LN’s removed
  - Robotic = 19 (8 - 40)
  - Open = 16 (6 - 35)

UNC Experience

• 326 pts underwent robotic radical cystectomy (Jan 2006 – October 2011)
  - 231 male + 95 female
  - 76% of cystectomies (n=429) during this time

Pelvic Lymphadenectomy

• Obturator / hypogastric LND
• Common iliac LND
• Para-aortic (+ pre-sacral) LND

Can we replicate with robotics?

• Surgeon can do whatever lymphadenectomy he/she does open
• Robot itself does not limit extent of dissection / template

Priorities

• Oncologic outcomes
  - RFS and DSS (2-yr and 5-yr)
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  - Morbidity
    - Peri-operative outcomes
      - EBL, Pain, Bowel recovery, Discharge, Complications
    - Functional recovery
      - Return to activities, urinary function, sexual function
  - Other
    - Learning curve
    - Costs

<table>
<thead>
<tr>
<th>Author</th>
<th>No.</th>
<th>OR Time (mins)</th>
<th>EBL (ml)</th>
<th>Hospital Stay (days)</th>
<th>% Comp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menon (2003)</td>
<td>17</td>
<td>298</td>
<td>150</td>
<td>n/a</td>
<td>-</td>
</tr>
<tr>
<td>Pruthi (2007)</td>
<td>20</td>
<td>366</td>
<td>313</td>
<td>5</td>
<td>25%</td>
</tr>
<tr>
<td>Wang (2007)</td>
<td>33</td>
<td>390</td>
<td>400</td>
<td>5</td>
<td>21%</td>
</tr>
<tr>
<td>Murphy (2008)</td>
<td>23</td>
<td>397</td>
<td>278</td>
<td>12</td>
<td>20%</td>
</tr>
<tr>
<td>Castle (2009)</td>
<td>80</td>
<td>275</td>
<td>225</td>
<td>5</td>
<td>28%</td>
</tr>
<tr>
<td>Kaufman (2009)</td>
<td>79</td>
<td>360</td>
<td>400</td>
<td>5</td>
<td>46% (11%)</td>
</tr>
<tr>
<td>IRCC (2009)</td>
<td>528</td>
<td>328</td>
<td>426</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>Pruthi (2010)</td>
<td>100</td>
<td>276</td>
<td>271</td>
<td>5</td>
<td>36% (8%)</td>
</tr>
<tr>
<td>Multi (2010)</td>
<td>227</td>
<td>327</td>
<td>256</td>
<td>5.5</td>
<td>30% (7%)</td>
</tr>
</tbody>
</table>
Statistical Analysis

- **Univariate Analysis:**
  - Continuous Variables: T-test
  - Categorical Variables: Chi-square

- **Multivariate Analysis:**
  - Generalized linear models
  - Outcomes:
    - Operative: EBL, Operative Time, Lymph Node Count
    - Post-Operative: Clavien complications, Days to First Bowel Movement/Flatus, Length of Stay
  - Covariates: Age, Sex, BMI, Pathologic stage
  - Predictor: Cystectomy Type (open vs. robotic)

**Randomized Trial**

<table>
<thead>
<tr>
<th></th>
<th>Robotic (n=20)</th>
<th>Open (n=21)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean EBL</td>
<td>258 ml</td>
<td>575 ml</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>OR Time</td>
<td>4.20 hrs</td>
<td>3.32 hrs</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Time to Flatus</td>
<td>2.3 days</td>
<td>3.2 days</td>
<td>0.0013</td>
</tr>
<tr>
<td>Time to BM</td>
<td>4.2 days</td>
<td>4.3 days</td>
<td>0.0008</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>5.1 days</td>
<td>6.0 days</td>
<td>0.2387</td>
</tr>
<tr>
<td>In-House Analg (Morphine)</td>
<td>89.0 mg</td>
<td>147.4 mg</td>
<td>0.0044</td>
</tr>
<tr>
<td>Clavien Units</td>
<td>2.3</td>
<td>2.6</td>
<td>0.5622</td>
</tr>
</tbody>
</table>

**Post Operative Pain**

- Postoperative Pain after Robot-Assisted Radical Cystectomy

**Complications**

- 100 consecutive patients
- 41 complications in 36 patients
  - 8% Clavien Grade 3+

**Critical analysis of complications after robotic-assisted radical cystectomy with identification of preoperative and operative risk factors**

- Robotic was independent predictor of lower complications (vs. open)
- 90 day comp. rate = 49%
  - N = 79; 58% ASA 3-4
- Most low grade (infectious (41%), or GI (27%))
- High grade
  - 16 complications in 13 pts (16%)
- Factors predicting high grade complications
  - Age >65 yo (RR=13), IV fluids > 5000 ml (RR=42), EBL > 500 cc (RR=10)

**Raynor, AUA (2010)**
Priorities

• Oncologic outcomes
  – RFS and DSS (2-yr and 5-yr)
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• Morbidity
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    • EBL, Pain, Bowel recovery, Discharge, Complications
  – Functional recovery
    • Return to activities, urinary function, sexual function

• Other
  – Learning curve
  – Costs

What is the long-term Impact?

• Assessment of QOL using FACT-BL and SF-12

• 52 Patients undergoing radical cystectomy (open and robotic)

• Mean FU = 24.8 months

Long-term QOL Impact

• No difference (open vs. robotic) in any FACT-BL or SF domains except:
  – Interest in sex (BL4) (p=0.011)
  – Ability to have/maintain an erection (BL5) (p=0.035)

<table>
<thead>
<tr>
<th>GP</th>
<th>GS</th>
<th>GE</th>
<th>GF</th>
<th>AC</th>
<th>PCS</th>
<th>MCS</th>
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</thead>
<tbody>
<tr>
<td>Robotic (n=33)</td>
<td>8.6</td>
<td>20.9</td>
<td>7.0</td>
<td>20.1</td>
<td>14.4</td>
<td>43.9</td>
</tr>
<tr>
<td>Open (n=19)</td>
<td>4.3</td>
<td>22.0</td>
<td>6.1</td>
<td>21.8</td>
<td>12.1</td>
<td>42.2</td>
</tr>
<tr>
<td>p value</td>
<td>0.168</td>
<td>0.496</td>
<td>0.446</td>
<td>0.328</td>
<td>0.117</td>
<td>0.655</td>
</tr>
</tbody>
</table>

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Learning Curve

• Transitioning from open to robotic techniques can be daunting

• Little report or description of experience of learning curve with regard to radical cystectomy

Pruthi et al, J Endo (2009)
Smith et al, J Urol (2010)
**Blood Loss**

Robotic Cystectomy Learning Curve: Blood Loss

- Blood loss (mL) vs Case Number
- Median blood loss stabilizes after approximately 20 cases

**Operative Time**

Robotic Cystectomy Learning Curve: Operative Time

- OR Time (Hours) vs Case Number
- Operative time stabilizes after approximately 40 cases

**Lymph Node Count**

Robotic Cystectomy Learning Curve: Lymph Node Count

- Lymph node count vs Case Number
- Consistency in lymph node count across cases

**Learning Curve: Conclusions**

- Learning curve of robotic cystectomy is a teachable and learnable technique
  - After 20 cases, no significant difference in blood loss
  - After 40 cases, no significant difference in operative time
  - No significant differences in margins, lymph node count, return of bowel function, and length of stay among quintiles
- For those competent in robotic prostatectomy techniques, adopting robotic technique for cystectomy is a feasible process

**Priorities**

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**What are the costs of robotic cystectomy?**

- Robotic approaches in urologic surgery are increasing
- Financial cost is an important consideration
- Robotic prostatectomy has been evaluated
  - Some report increased costs overall
  - Others describe cost equivalence in high volume centers
- Cost analysis reports on robotic cystectomy lacking

**Notes**

- Pruthi et al, J Endo (2009)
- Smith et al, J Urol (2010)
Financial Costs
• Fixed OR costs
  – Base OR costs
  – Robotic investment and instruments ($2,303/case)
  – Maintenance
• Variable OR costs
  – Anesthesia (per time)
  – OR personnel (per time)
• Hospital costs
  – Hospital cost per day ($940/day)
  – Transfusion cost per unit ($268/unit)

Results
<table>
<thead>
<tr>
<th>Costs</th>
<th>Open</th>
<th>Robotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Fixed</td>
<td>$2,398</td>
<td>$4,032</td>
</tr>
<tr>
<td>OR Variable</td>
<td>$7,228</td>
<td>$7,798</td>
</tr>
<tr>
<td>Hospital</td>
<td>$4,982</td>
<td>$4,418</td>
</tr>
<tr>
<td>Mean</td>
<td>$14,608</td>
<td>$16,248</td>
</tr>
</tbody>
</table>

Difference of $1640

Costs Summary
• Robotic Cystectomy
  – Higher OR fixed costs ($1,634)
  – Higher OR variable costs ($570)
• Open Cystectomy
  – Higher hospital costs ($564)

Costs – Re-analysis
• Utilizing RCT (Nix et al, 2009) (n = 41)

<table>
<thead>
<tr>
<th>Costs</th>
<th>ORC (95% CI)</th>
<th>RMC (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall costs†</td>
<td>$19,047 (16,675 - 21,030)</td>
<td>$19,637 (18,297 - 22,312)</td>
</tr>
<tr>
<td>OR fixed‡</td>
<td>$5,742</td>
<td>$6,202</td>
</tr>
<tr>
<td>OR dispos.</td>
<td>$5,875</td>
<td>$5,880</td>
</tr>
<tr>
<td>OR capital</td>
<td>$2,658</td>
<td>$2,649</td>
</tr>
<tr>
<td>Post-op hospital costs†</td>
<td>$2,667</td>
<td>$3,907</td>
</tr>
</tbody>
</table>

Not significantly different

Conclusion
• Unclear if robotic cystectomy is associated with higher financial cost compared to open in peri-operative setting
  – Primary difference related to robotic costs
• Does not evaluate potential financial impact of multiple other factors
  – Morbidity
  – Time of outpatient convalescence
  – Overall disability

Robotic vs. Open
• Comparable
  – surgical margin status
  – lymph node yield
  – long-term QOL
• Potential Benefits
  – EBL
  – recovery of bowel function
  – pain
• Potential Negatives
  – OR time
  – Costs (maybe)

Long-term oncologic outcomes still remain uncertain
Future Directions

- Increased worldwide experience
- Long-term oncologic assessment
- Multi-institutional RCT
- Intracorporeal urinary diversion

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