Systematic Endoscopic Evaluation in Predicting pT0 Bladder Cancer: A Prospective Trial

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Background

- Radical Cystectomy (RC) with neoadjuvant chemotherapy (NAC) is the gold standard for muscle invasive bladder cancer (MIBC)
- Up to ~30% of patients are found to be pT0 after NAC\(^1\)
- Discordance between endoscopy/biopsy vs. final pathology drives management
  - Rethink “no bladder left behind” ethos
- Objective: Assess reliability of Systematic Endoscopic Evaluation (SEE) at RC to predict patients who no longer harbor malignancy

Methods

- Single Institution, prospective, non-randomized, IRB-approved cohort study
- Patients undergoing RC underwent SEE per protocol
  - All patients undergoing RC for bladder cancer were offered to participate
  - Anesthesia induction → SEE → RC
  - Biopsy/TUR of any tumor/scar, plus 2 random sites
  - RC was performed regardless of findings on SEE
- A novel bladder map and grading system used to describe lesions
- Endoscopic findings, biopsy results, and final pathology were compared
- Early stopping rule: NPV < 70%
At each cystoscopic examination, the location and extent of tumor volume will be visually depicted and graded according to the following table and diagrams. For example, a 4cm papillary mass with calcifications located near the previous resection site at the right ureteral orifice would be graded as “3HCD” and hand-drawn in the corresponding quadrant near the right ureteral orifice. Normal mucosa will not be graded or depicted on diagram.

Table 1 Grading system for cystoscopic assessment of tumor volume.

<table>
<thead>
<tr>
<th>Lesion Score</th>
<th>Size</th>
<th>Lesion Subscript</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>Random Biopsy</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Healed Scar</td>
<td>A  Sessile lesion</td>
</tr>
<tr>
<td>1</td>
<td>Erythema</td>
<td>B  Papillary lesion</td>
</tr>
<tr>
<td>2</td>
<td>Mass &lt; 3 cm</td>
<td>C  Calcified lesion</td>
</tr>
<tr>
<td>3</td>
<td>Mass 3-5 cm</td>
<td>D  Apparent previous resection site</td>
</tr>
<tr>
<td>4</td>
<td>Mass &gt; 5 cm</td>
<td></td>
</tr>
</tbody>
</table>
Results

- N=61
  - Indication: MIBC (N=41; 67%) & High Risk NMIBC (N=20; 33%)
- 38 patients received NAC
- Pathological Outcomes:
  - pT0: 16 pts (26%)
  - NMIBC: 17 pts (28%)
  - MIBC (≥pT2): 28 pts (46%)

<table>
<thead>
<tr>
<th>SEE Characteristics:</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEE Characteristics:</td>
<td>64.4%</td>
<td>93.8%</td>
<td>96.7%</td>
<td>48.4%</td>
</tr>
</tbody>
</table>

- Sensitivity for ≥pT2: 71%
SEE T0→pT2
Conclusion

• 1st prospective trial to explore potential of SEE to predict final pathologic stage.
• Early trial closure due to NPV below preset limit
• pT2 or higher disease was missed nearly 30% of the time
• Current cystoscopic techniques are inadequate to guide decisions on bladder preservation.

Special Thanks: