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

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FOX CHASE CANCER CENTER
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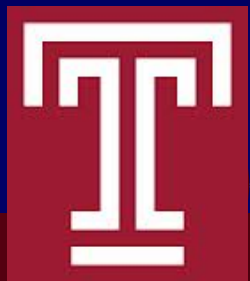
Background

- 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

1. Millikan, et al. Journal of clinical oncology, 2001

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%

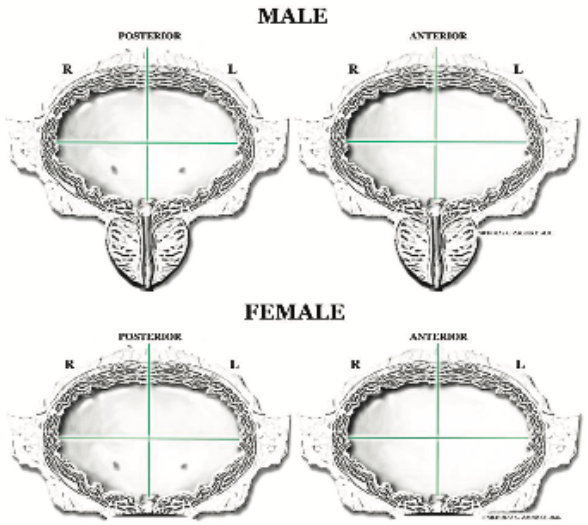


Bladder Map

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 "3_{BCD}" 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.

Lesion Score	Size	Lesion Subscript
X	Random Biopsy	
0	Healed Scar	
1	Erythema	A Sessile lesion
2	Mass < 3 cm	B Papillary lesion
3	Mass 3-5 cm	C Calcified lesion
4	Mass > 5 cm	D Apparent previous resection site



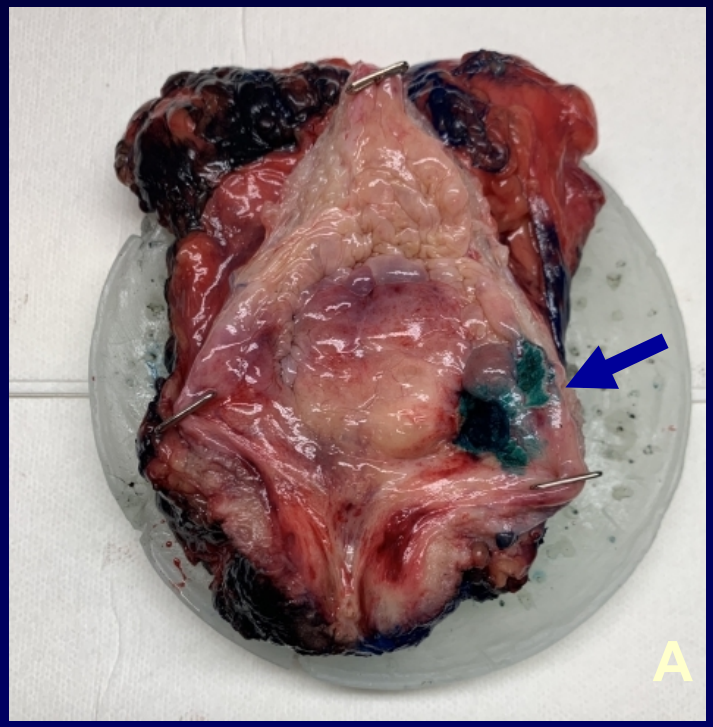
Results

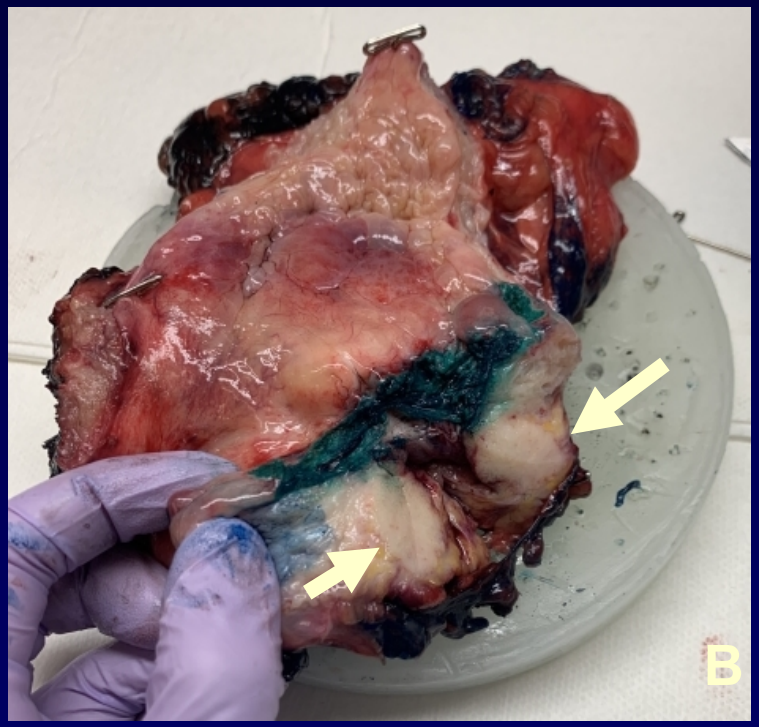
- N=61
  - Indication: MIBC (N=41; 67%) & High Risk NMIBC (N=20; 33%)
- 38 patients received NAC
- Pathological Outcomes:
  - pT0: 16 pts (26%)
  - NMIBC: 17 pts (28%)
  - MIBC (≥pT2) : 28 pts (46%)

	Sensitivity	Specificity	PPV	NPV
SEE Characteristics:	64.4%	93.8%	96.7%	48.4%

- 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.

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