

AUA Guidelines for Invasive Bladder Cancer: What's New?"

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History

- 1999: AUA guidelines Panel Non-muscle invasive bladder cancer (AUA) – Smith et al
- ↓
- 2009: Update AUA guidelines Panel Non-muscle invasive bladder cancer (AUA) – Hall et al
- ↓
- 2016: Update AUA guidelines Panel Non-muscle invasive bladder cancer (AUA/SUO) – Chang et al
- ↓
- 2017: Treatment of Non-Metastatic Muscle-Invasive Bladder Cancer: AUA/ASCO/ASTRO/SUO Guideline

Guideline Review

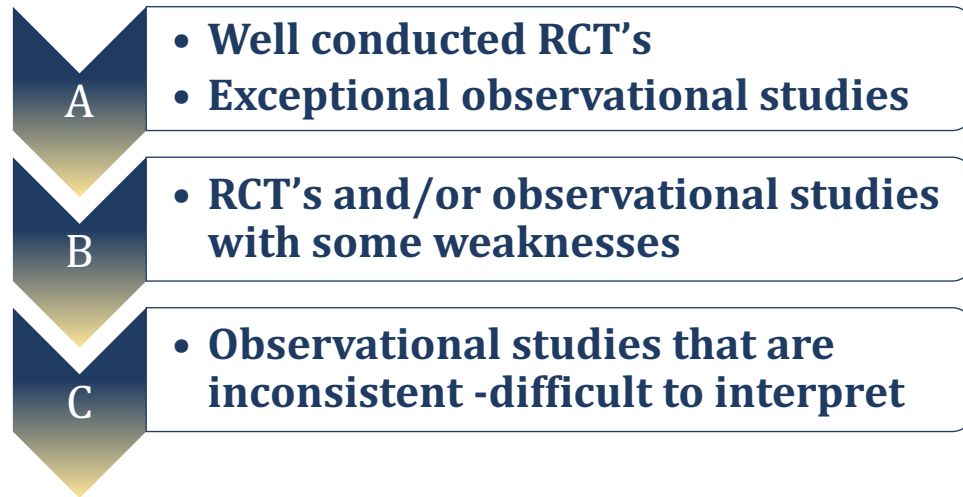
AHRQ SYSTEMATIC REVIEW

- January 1990- October 2014

Two investigators independently assessed the risk of bias for all randomized trials and observational studies and assigned ratings of “high,” “medium,” or “low” risk of bias.

Methodology

- Grading of Guidelines:



Methodology

<p>Strong Recommendation</p> <p>(Net benefit or harm substantial)</p>	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) is substantial • Applies to most patients in most circumstances and future research is unlikely to change confidence 	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) is substantial • Applies to most patients in most circumstances but better evidence could change confidence 	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) appears substantial • Applies to most patients in most circumstances but better evidence is likely to change confidence • (rarely used to support a Strong Recommendation)
<p>Moderate Recommendation</p> <p>(Net benefit or harm moderate)</p>	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) is moderate • Applies to most patients in most circumstances and future research is unlikely to change confidence 	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) is moderate • Applies to most patients in most circumstances but better evidence could change confidence 	<ul style="list-style-type: none"> • Benefits > Risks/Burdens (or vice versa) • Net benefit (or net harm) appears moderate • Applies to most patients in most circumstances but better evidence is likely to change confidence
<p>Conditional Recommendation</p> <p>(no apparent net benefit or harm)</p>	<ul style="list-style-type: none"> • Benefits = Risks/Burdens • Best action depends on individual patient circumstances • Future research unlikely to change confidence 	<ul style="list-style-type: none"> • Benefits = Risks/Burdens • Best action appears to depend on individual patient circumstances • Better evidence could change confidence 	<ul style="list-style-type: none"> • Balance between Benefits & Risks/Burdens unclear • Alternative strategies may be equally reasonable • Better evidence likely to change confidence

Principle vs. Expert Opinion

CLINICAL PRINCIPLE

- A statement about a component of clinical care that is very **widely agreed upon by urologists** or other clinicians for which there **may or may not be evidence in the medical literature.**


EXPERT OPINION

- A statement, **achieved by consensus of the Panel**, that is based on members' clinical training, experience, knowledge, and judgment for which **there is no published evidence.**

Epidemiology

- 79,000 new cases in 2017
- 16, 870 deaths in 2017
- 25% of newly diagnosed patients present with muscle invasive disease

Estimated New Cases

			Males
Prostate	161,360	19%	
Lung & bronchus	116,990	14%	
Colon & rectum	71,420	9%	
Urinary bladder	60,490	7%	
Melanoma of the skin	52,170	6%	
Kidney & renal pelvis	40,610	5%	
Non-Hodgkin lymphoma	40,080	5%	
Leukemia	36,290	4%	
Oral cavity & pharynx	35,720	4%	
Liver & intrahepatic bile duct	29,200	3%	
All Sites	836,150	100%	

Guidelines

- 35 statements total:
- Initial Patient Evaluation and Counseling: #1-5
- Treatment (Chemotherapy): #6-9
- Treatment (Radical Cystectomy): #10-14
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- Bladder Preservation: #21-29
- Surveillance: #30-35

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INITIAL PATIENT EVALUATION & COUNSELING

1. Prior to treatment consideration, a full history and physical exam should be performed, including an exam under anesthesia, at the time of transurethral resection of bladder tumor for a suspected invasive cancer. (Clinical Principle)
 - H&P, PE, exam under anesthesia at TURBT
2. Prior to muscle-invasive bladder cancer management, clinicians should perform a complete staging evaluation, including imaging of the chest and cross sectional imaging of the abdomen and pelvis with intravenous contrast if not contraindicated. Laboratory evaluation should include a CMP and CBC. (Clinical Principle)
 - Imaging: chest, cross sectional abd/pelvis w contrast (if not contraindicated)
 - Labs: CBC, CMP

INITIAL PATIENT EVALUATION & COUNSELING

3. An experienced genitourinary pathologist should review the pathology of a patient when variant histology is suspected or if muscle invasion is equivocal (e.g., micropapillary, nested, plasmacytoid, neuroendocrine, sarcomatoid, extensive squamous or glandular differentiation). (Clinical Principle)

- Variant Histology should be re-viewed by GU trained pathologist
- Up to 1/3 treatment strategies changed after review by GU Pathologist
- Variant Histologies → More locally advanced compared to UC bladder

INITIAL PATIENT EVALUATION & COUNSELING

Selected urothelial carcinoma variants and their treatment	
Squamous	Higher risk of upstaging, local recurrence can be high
Small cell	Systemic Chemotherapy → observation, RC, XRT
Plasmacytoid	Aggressive cancer → immediate RC, has predilection for carcinomatosis
Micropapillary	Aggressive cancer → immediate RC +/- neoadjuvant chemo**
Sarcomatoid	Aggressive cancer → immediate RC
Nested/large nested	Aggressive cancer → immediate RC
Adenocarcinoma	-- Can consider partial cystectomy if urachal/dome -- evaluate for GI adenocarcinoma

INITIAL PATIENT EVALUATION & COUNSELING

4. For patients with newly diagnosed muscle-invasive bladder cancer, curative treatment options should be discussed before determining a plan of therapy that is based on both patient comorbidity and tumor characteristics. Patient evaluation should be completed using a multidisciplinary approach. (Clinical Principle)
- **Multi-disciplinary discussion:**
 - **Cysectomy +/- Neoadj Chemotherapy**
 - **Trimodal Therapy: TURBT + Chemotherapy +Radiotherapy**

INITIAL PATIENT EVALUATION & COUNSELING

5. Prior to treatment, clinicians should counsel patients regarding complications and the implications of treatment on quality of life (e.g., impact on continence, sexual function, fertility, bowel dysfunction, metabolic problems). (Clinical Principle)

- **Complication impact on QOL discussion**
- **Both: sexual and urinary**
- **Cystectomy:**
 - **Complication: 60% Grade 2-5 Clavien complication rate (Recent RCT)**
 - **Readmission RC: 10-30%**
 - **Diversion related QOL: continence, metabolic**
- **Trimodal Therapy**
 - **Early and late GU/GI toxicity**
 - **Long term follow-up with cystoscopy**

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TREATMENT: CHEMOTHERAPY (NAC/AC)

6. Utilizing a multidisciplinary approach, clinicians should offer cisplatin-based neoadjuvant chemotherapy to eligible radical cystectomy patients prior to cystectomy. (Strong Recommendation; Evidence Level: Grade B)

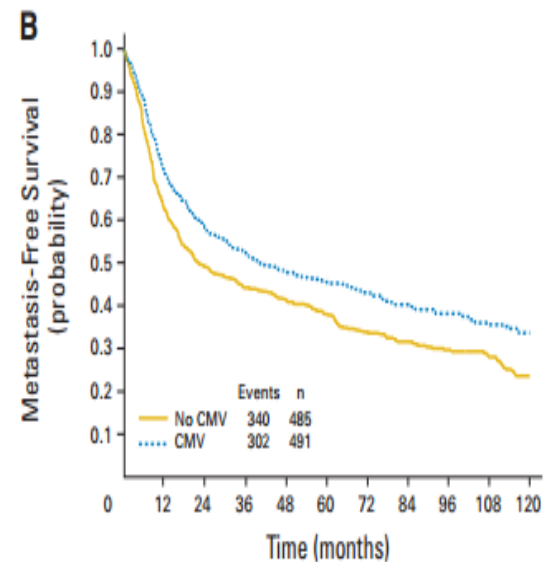
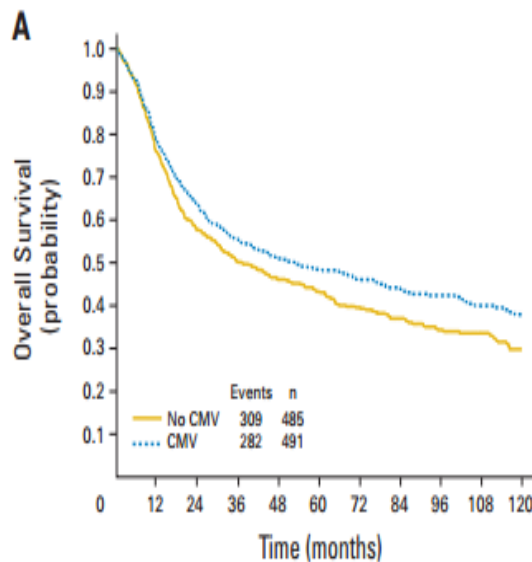
- Neoadjuvant Cisplatin based chemo should be offered

TREATMENT: CHEMOTHERAPY (NAC/AC)

International Phase III Trial Assessing Neoadjuvant Cisplatin, Methotrexate, and Vinblastine Chemotherapy for Muscle-Invasive Bladder Cancer: Long-Term Results of the BA06 30894 Trial

International Collaboration of Trialists on behalf of the Medical Research Council Advanced Bladder Cancer Working Party (now the National Cancer Research Institute Bladder Cancer Clinical Studies Group), the European Organisation for Research and Treatment of Cancer Genito-Urinary Tract Cancer Group, the Australian Bladder Cancer Study Group, the National Cancer Institute of Canada Clinical Trials Group, Finnbladder, Norwegian Bladder Cancer Study Group, and Club Urológico Español de Tratamiento Oncológico Group

- N=976, RC or RT vs. CMV + RC or RT
- 16% reduction in cancer specific mortality
- Increase 3-year cancer-specific survival from 50 to 56%

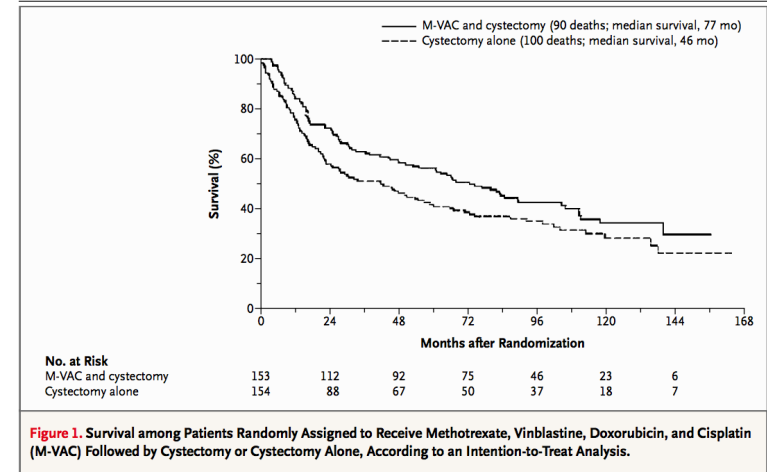


TREATMENT: CHEMOTHERAPY (NAC/AC)

Neoadjuvant Chemotherapy plus Cystectomy Compared with Cystectomy Alone for Locally Advanced Bladder Cancer

H. Barton Grossman, M.D., Ronald B. Natale, M.D., Catherine M. Tangen, Dr.P.H.,
V.O. Speights, D.O., Nicholas J. Vogelzang, M.D., Donald L. Trump, M.D.,
Ralph W. deVere White, M.D., Michael F. Sarosdy, M.D., David P. Wood, Jr., M.D.,
Derek Raghavan, M.D., Ph.D., and E. David Crawford, M.D.

- N=317, RC vs. MVAC + RC
- cT2-cT4 N0
- Median OS: 77 versus 46 months, p=0.05
- Higher pT0 rate: 38% vs 15%



Grossman et al 2003

TREATMENT: CHEMOTHERAPY (NAC/AC)

- Utilization lags behind the data
- 7.6% → 20.9% utilization from 2006-2010
- Reasons:
 - Overtreatment
 - Delay in treatment if no response
 - Toxicity
 - Modest Survival benefit

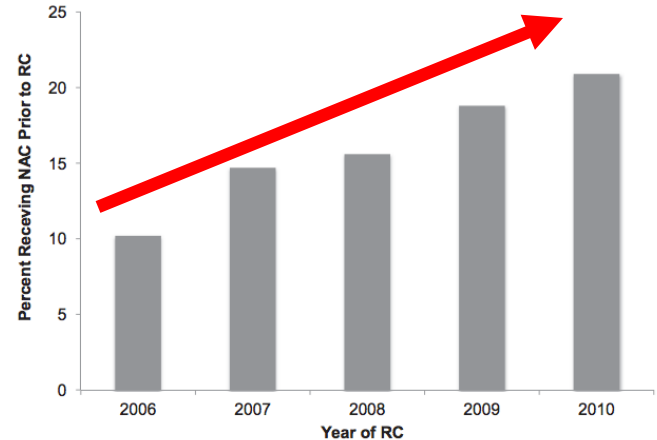


Figure 1. Use of neoadjuvant chemotherapy (NAC) increased with time for patients undergoing radical cystectomy (RC). The difference between 2006 (7.6%) and 2010 (20.9%) reached significance ($P < .01$).

Zaid et al 2014

TREATMENT: CHEMOTHERAPY (NAC/AC)

- MD Anderson risk adapted approach
- Retrospective
- Not validated

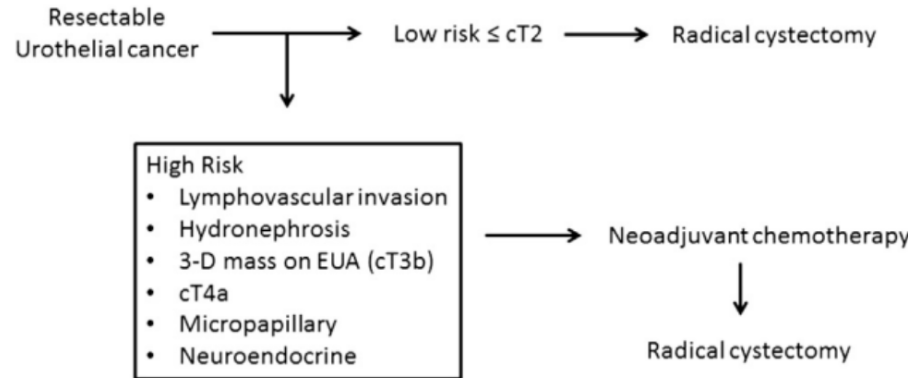


Figure 4. Neoadjuvant platform for clinical based staging and therapy for bladder cancer.

TREATMENT: CHEMOTHERAPY (NAC/AC)

- There are no validated predictive factors or clinical characteristics (including age) associated with an increased or decreased probability of response and benefit
- The best regimen and duration for cisplatin-based NAC remains undefined
- The decision regarding eligibility for cisplatin-based NAC should be based on comorbidities and performance status, including cardiac status and presence of peripheral neuropathy, hearing loss, and renal dysfunction

TREATMENT: CHEMOTHERAPY (NAC/AC)

7. Clinicians should not prescribe carboplatin-based neoadjuvant chemotherapy for clinically resectable stage cT2-T4aN0 bladder cancer. Patients ineligible for cisplatin-based neoadjuvant chemotherapy should proceed to definitive locoregional therapy. (Expert Opinion)

- No Carboplatin (patients who are cisplatin ineligible)
- Proceed to definitive treatment

TREATMENT: CHEMOTHERAPY (NAC/AC)

8. Clinicians should perform radical cystectomy as soon as possible following a patient's completion of and recovery from neoadjuvant chemotherapy. (Expert Opinion)
- Timely Cystectomy after Neoadj chemo
 - ~4 weeks (depending on patient's functional status, CBC)

TREATMENT: CHEMOTHERAPY (NAC/AC)

9. Eligible patients who have not received cisplatin-based neoadjuvant chemotherapy and have non-organ confined (pT3/T4 and/or N+) disease at cystectomy should be offered adjuvant cisplatin-based chemotherapy. (Moderate Recommendation; Evidence Level: Grade C)
- Adjuvant Cisplatin based chemo should be offered pT3/pT4/ and or N+
 - All adj chemo trials underpowered, terminated early
 - Meta-analyses have demonstrated possible benefit (quality of data variable)

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TREATMENT: RADICAL CYSTECTOMY

10. Clinicians should offer radical cystectomy with bilateral pelvic lymphadenectomy for surgically eligible patients with resectable non-metastatic (M0) muscle-invasive bladder cancer. (Strong Recommendation; Evidence Level: Grade B)

- **RC + Bilateral PLND should be performed**

11. When performing a standard radical cystectomy, clinicians should remove the bladder, prostate, and seminal vesicles in males and should remove the bladder, uterus, fallopian tubes, ovaries, and anterior vaginal wall in females. (Clinical Principle)

- **Remove adjacent organs at highest risk of harboring disease**
 - **Male: Prostate, SVs**
 - **Female: Uterus, fallopian tubes, ovaries, anterior vaginal wall**

TREATMENT: RADICAL CYSTECTOMY

12. Clinicians should discuss and consider sexual function preserving procedures for patients with organ-confined disease and absence of bladder neck, urethra, and prostate (male) involvement. (Moderate Recommendation; Evidence Level: Grade C)

- Consider sexual preservation
 - Vaginal sparing, ovarian sparing
 - Periprostatic nerve sparing

TREATMENT: RADICAL CYSTECTOMY

13. In patients undergoing radical cystectomy, ileal conduit, continent cutaneous, and orthotopic neobladder urinary diversions should all be discussed. (Clinical Principle)

- Consider QOL with diversion choice

TREATMENT: RADICAL CYSTECTOMY

14. In patients receiving an orthotopic urinary diversion, clinicians must verify a negative urethral margin. (Clinical Principle)

- Verify negative urethral margin
- Risk of cancer in retained urethra can be between 1%-17%
- Reported risk factors:
 - tumor multifocality
 - papillary pattern
 - CIS/tumor at the bladder neck
 - prostatic urethral involvement and prostatic stromal invasion**
(should not preclude neobladder → frozen section)

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Perioperative Management

15. Clinicians should attempt to optimize patient performance status in the perioperative setting. (Expert Opinion)

- Optimization of patient performance status
- Nutritional counseling
- Smoking cessation
- Physical Conditioning

Perioperative Management

Pre-Op

- Counseling
- No mechanical bowel preparation
- Carbohydrate loading
- Avoidance of prolonged NPO
- Adequate VTE prophylaxis
- Appropriate anti-microbial prophylaxis

Operative

- Analgesic protocol with epidural analgesia
- Conservative fluid management
- Prevention of hypothermia

Post-Op

- Removal of NG tube before PACU
- Avoidance opioids
- Aggressive control of nausea/vomiting
- Early ambulation
- Early Feeding

Discharge

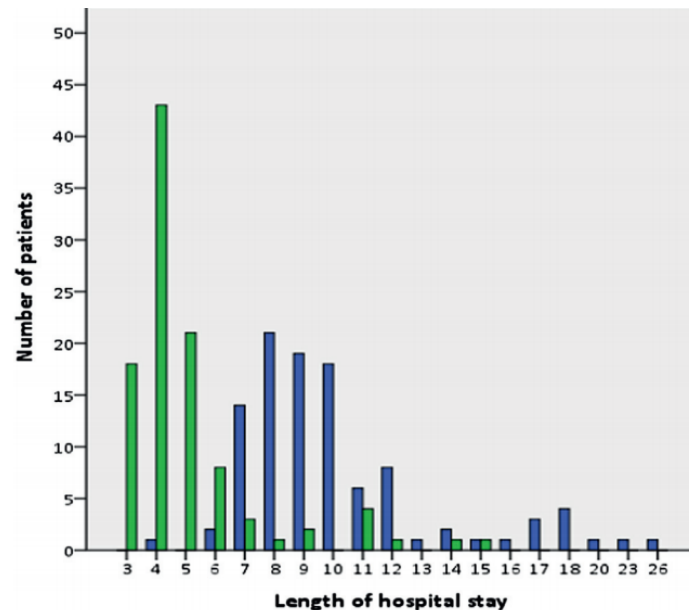
- Enterostomal therapy
- Patient education
- Caretaker education
- Survivorship

Perioperative Management

Enhanced Recovery Protocol after Radical Cystectomy for Bladder Cancer

Siamak Daneshmand,* † Hamed Ahmadi, Anne K. Schuckman, ‡ Anirban P. Mitra, Jie Cai, Gus Miranda and Hooman Djaladat

- N=110 patients,
- Median LOS 4 days
- 82% BM on POD 2
- 30 day readmission rate: 21%



Perioperative Management

16. Perioperative pharmacologic thromboembolic prophylaxis should be given to patients undergoing radical cystectomy. (Strong Recommendation; Evidence Level: Grade B)

- VTE prophylaxis
- Optimal Perioperative timing and duration still undetermined
- Consider extended DVT proph for 30 days post-op (up to 15% may experience post-op DVT)
- >50% VTE occur after discharge

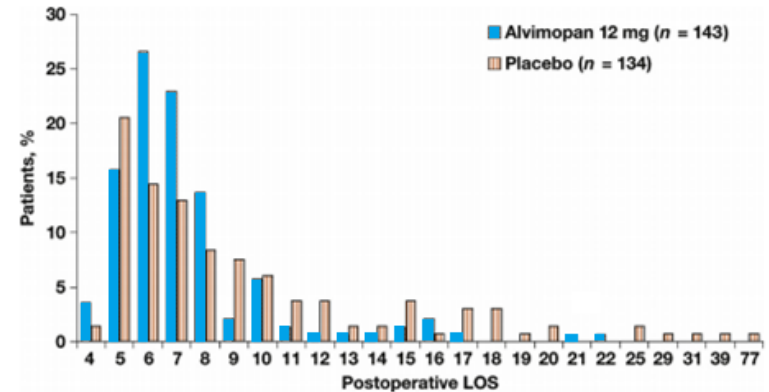
Perioperative Management

17. In patients undergoing radical cystectomy μ -opioid antagonist therapy should be used to accelerate gastrointestinal recovery, unless contraindicated. (Strong Recommendation; Evidence Level: Grade B)

- Entereg (Alvimopan) post-op:

Perioperative Management

- **Entereg (Alvimopan) post-op:**
- Time bowel function: (5.5 versus 6.8 days, $p < 0.001$)
- Shorter LOS (7.4 versus 10.1 days; $p = 0.005$).
 - First dose is given just prior to surgery and then continued until diet is tolerated or for a maximum of 15 doses (7 days)
 - No opioids 7 days prior



Perioperative Management

18. Patients should receive detailed teaching regarding care of urinary diversion prior to discharge from the hospital. (Clinical Principle)

- **Urinary Diversion Patient Education is Paramount**
- Ostomy teaching
- Continent diversion teaching
- Home health assistance post-op

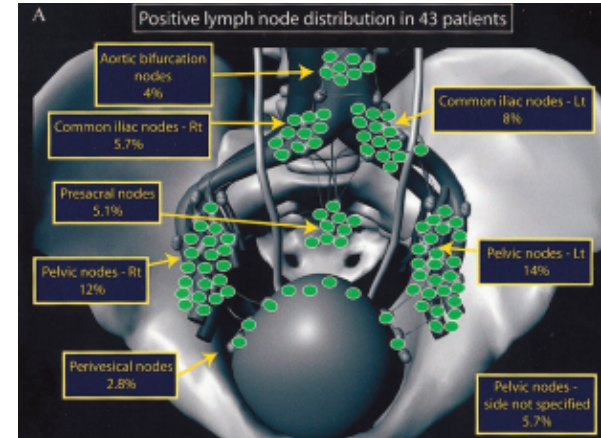
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Treatment: Pelvic Lymphadenectomy

19. Clinicians must perform a bilateral pelvic lymphadenectomy at the time of **any surgery with curative intent**. (Strong Recommendation; Evidence Level: Grade B)

- **PLND with any surgery with curative intent**
 - Radical Cystectomy
 - Partial Cystectomy



Treatment: Pelvic Lymphadenectomy

20. When performing bilateral pelvic lymphadenectomy, clinicians should remove, at a minimum, the external and internal iliac and obturator lymph nodes (standard lymphadenectomy). (Clinical Principle)

- **At minimum remove:**
 - Obturator nodes
 - External/internal iliac nodes

ADD RCT trial LERNER

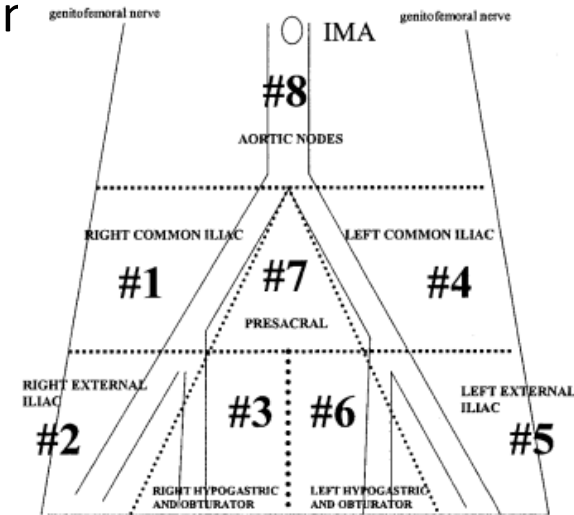


FIG. 1. Limits of standard and extended lymph node dissections. IMA, inferior mesenteric artery.

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BLADDER PRESERVATION: PATIENT SELECTION

21. For patients with newly diagnosed non-metastatic muscle-invasive bladder cancer who desire to retain their bladder, and for those with significant comorbidities for whom radical cystectomy is not a treatment option, clinicians should offer bladder preserving therapy when clinically appropriate. (Clinical principle)

- Selection: unfit for cystectomy or desire bladder preservation
- Panel preferred approach: → TURBT, systemic chemotherapy, radiation therapy, and ongoing cystoscopy to evaluate response

BLADDER PRESERVATION: PATIENT SELECTION

22. In patients under consideration for bladder preserving therapy, maximal debulking transurethral resection of bladder tumor and assessment of multifocal disease/carcinoma in situ should be performed. (Strong Recommendation; Evidence Strength: Grade C)

- TURBT consideration for bladder preservation therapy:
 - Maximal Resection
 - Assessment of Multifocal disease
 - CIS assessment
 - Tumor size

BLADDER PRESERVATION: MAXIMAL TURBT AND PARTIAL CYSTECTOMY

23. Patients with muscle-invasive bladder cancer who are medically fit and consent to radical cystectomy should not undergo partial cystectomy or maximal transurethral resection of bladder tumor as primary curative therapy. (Moderate Recommendation; Evidence Level: Grade C)

- The ideal patients for partial cystectomy have a, **no hydronephrosis, solitary, initial tumor without concomitant CIS** in the bladder or prostatic urethra that is **amenable to resection with a 2cm surgical margin**.
- *Literature review indicates that only **5% of patients** with invasive bladder cancer meet these criteria*

BLADDER PRESERVATION: PRIMARY RADIOTHERAPY

24. For patients with muscle-invasive bladder cancer, clinicians should not offer radiation therapy alone as a curative treatment. (Strong Recommendation; Evidence Level: Grade C)

- Do not offer radiation therapy alone:
- High rates of pelvic failure
- Five year local control rates of 31-50%
 - Likely an underestimate as those who develop metastatic disease are less likely to undergo continued bladder surveillance

MULTIMODAL BLADDER PRESERVATION THERAPY

25. For patients with muscle-invasive bladder cancer who have elected multimodal bladder preserving therapy, clinicians should offer maximal transurethral resection of bladder tumor, chemotherapy combined with external beam radiation therapy, and planned cystoscopic re-evaluation. (Strong Recommendation; Evidence Level: Grade B)

- Maximal TURBT + chemo + radiation
- Chemo → sensitizes tumor cells to radiation and control of occult metastases
- Consider Cystoscopic re-evaluation with biopsy (advocated during middle of RT)

MULTIMODAL BLADDER PRESERVATION THERAPY

- Maximal TURBT + chemo + radiation
 - **Ideal candidate**
 - 1) unifocal tumor <3cm
 - 2) no carcinoma in situ (CIS),
 - 3) no evidence of hydronephrosis, and
 - 4) a tumor that can be completely transurethrally resected

MULTIMODAL BLADDER PRESERVATION THERAPY

Table 2. Pooled Long-Term Outcomes

Outcome	No. of Patients	5 Years			10 Years		
		Estimate (%)	95% CI (%)	No. of Patients at Risk	Estimate (%)	95% CI (%)	No. of Patients at Risk
Local failure, any	212	43	39 to 48	148	48	43 to 53	39
Local failure, muscle invasive	56	13	10 to 17	191	14	10 to 17	52
Local failure, non-muscle invasive	156	31	27 to 36	162	36	32 to 41	44
Nodal recurrence	66	13	10 to 16	199	16	12 to 19	54
Distant metastases	153	31	27 to 36	188	35	30 to 39	53
Disease-specific survival	150	71	67 to 75	205	65	61 to 70	57
Bladder-intact disease-free survival	282	56	51 to 61	173	55	50 to 60	45
Overall survival	262	57	52 to 61	205	36	31 to 42	57

MULTIMODAL BLADDER PRESERVATION THERAPY

- It is unclear what proportion of patients who, having initially chosen bladder preservation, ultimately require cystectomy in a non-study setting.
- The reported bladder preservation rates may be dependent upon the degree of initial patient evaluation and selection

MULTIMODAL BLADDER PRESERVATION THERAPY

26. Radiation sensitizing chemotherapy regimens should include cisplatin or 5-fluorouracil and mitomycin C. (Strong Recommendation; Evidence Level: Grade B)

- Radiation sensitizers:
 - 5 FU + MMC
 - Cisplatin

MULTIMODAL BLADDER PRESERVATION THERAPY

27. Following completion of bladder preserving therapy, clinicians should perform regular surveillance with CT scans, cystoscopy, and urine cytology. (Strong Recommendation; Evidence Level: Grade C)

- Surveillance Strategy:
- Published protocols recommend every 3 month cystoscopy during the first year, every 4-6 months in the second, and every 6-12 months thereafter.
- Cross-sectional imaging of the abdomen and pelvis and chest imaging every six months for the first two years

MULTIMODAL BLADDER PRESERVATION THERAPY

28. In patients who are medically fit and have residual or recurrent muscle-invasive disease following bladder preserving therapy, clinicians should offer radical cystectomy with bilateral pelvic lymphadenectomy. (Strong Recommendation; Evidence Level: Grade C)

- If multimodal therapy fails → Radical cystectomy:
- Up to 30% of patients will have an invasive recurrence

MULTIMODAL BLADDER PRESERVATION THERAPY

29. In patients who have a non-muscle invasive recurrence after bladder preserving therapy, clinicians may offer either local measures, such as transurethral resection of bladder tumor with intravesical therapy, or radical cystectomy with bilateral pelvic lymphadenectomy. (Moderate Recommendation; Evidence Level: Grade C)

- Non-muscle invasive recurrence → TURBT, intravesical therapy, or RC:
- Case series show that NMIBC recurrences following bladder sparing therapy may still be managed by standard local measures similar to *de novo* NMIBC

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PATIENT SURVEILLANCE

30. Clinicians should obtain chest imaging and cross sectional imaging of the abdomen and pelvis with CT or MRI at 6-12 month intervals for 2-3 years and then may continue annually. (Expert Opinion)

- Radiographic evaluation of the abdomen and pelvis:
 - Detection of upper tract cancer
 - Disease detection in the most common sites of recurrence, progression, and metastasis
 - Urinary diversion concerns

PATIENT SURVEILLANCE

31. Following therapy for muscle-invasive bladder cancer, patients should undergo laboratory assessment at three to six month intervals for two to three years and then annually thereafter. (Expert Opinion)

- Lab evaluation: Electrolyte imbalances, B12 deficiency, acidosis

31. Following radical cystectomy in patients with a retained urethra, clinicians should monitor the urethral remnant for recurrence. (Expert Opinion)

- Monitor urethra for recurrence:
- 4-14% risk of recurrence in urethra
- Urethral Cytology can be low yield (no specific recommendation)
 - Consider in higher risk patients (pain or urethral bleeding at time of dx)

PATIENT SURVEILLANCE

33. Clinicians should discuss with patients how they are coping with their bladder cancer diagnosis and treatment and should recommend that patients consider participating in a cancer support group or consider receiving individual counseling. (Expert Opinion)

bcn.org

cancersupportcommunity.org

cancercare.org

bladdercancersupport.org

cancer.org

urologyhealth.org

34. Clinicians should encourage bladder cancer patients to adopt healthy lifestyle habits, including smoking cessation, exercise, and a healthy diet, to improve long-term health and quality of life. (Expert Opinion)

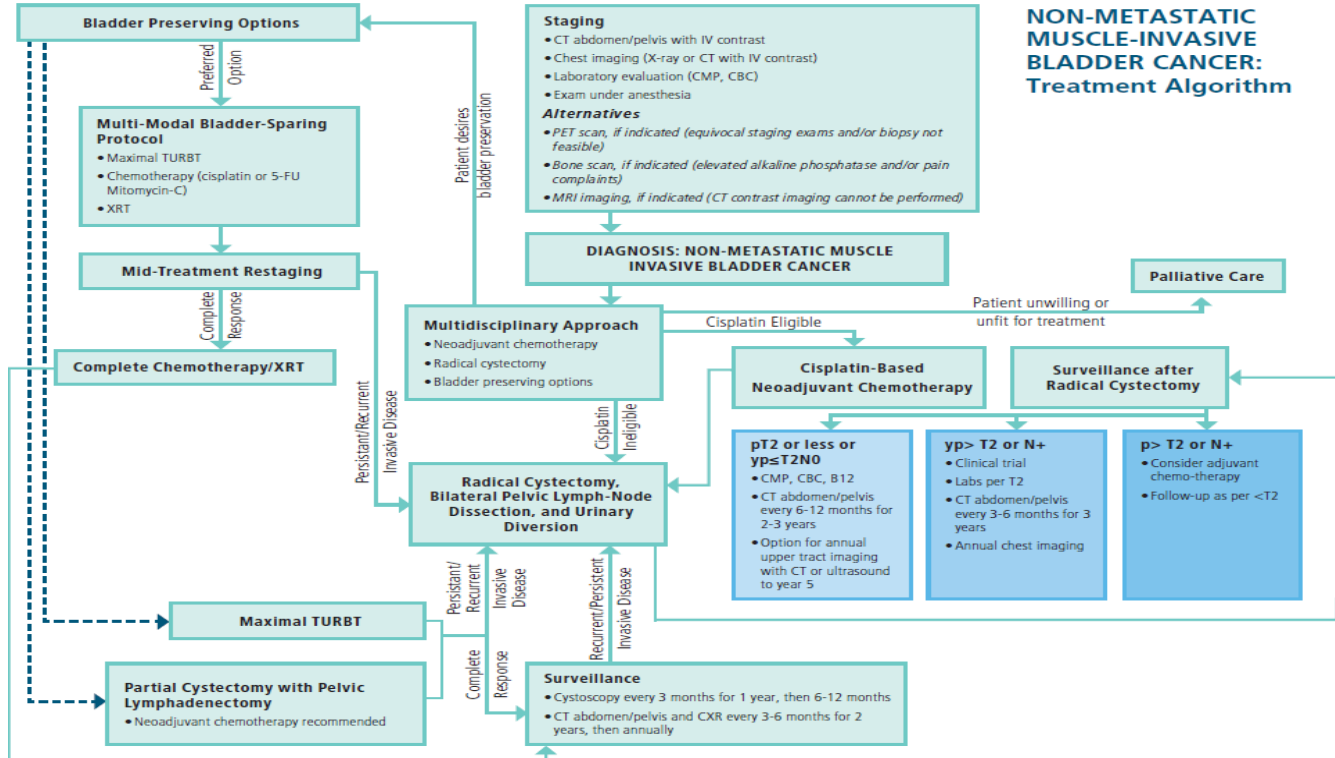
- [Survivorship:](#)

PATIENT SURVEILLANCE

35. In patients diagnosed with variant histology, clinicians should consider unique clinical characteristics that may require divergence from standard evaluation and management for urothelial carcinoma. (Expert Opinion)

- Modify standard evaluation for variant histology:

Summary



CBC= complete blood count; CMP= comprehensive metabolic panel; CXR= chest X-ray; p= pathologic stage; TURBT=trans-urethral resection of bladder tumor; XRT= external beam radiation therapy; yp= pathologic stage after neoadjuvant chemotherapy