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Original Article – Editor's choice

Optimal Management of Muscle-invasive Bladder Cancer: Recommendations from the International Bladder Cancer Group

Shilpa Gupta[a], *Roger Li*[b], *Patrick J. Hensley*[c], *Siamak Daneshmand*[d], *Bishoy M. Faltas*[e], *Petros Grivas*[f], *Niyati Lobo*[g], *Maria Carmen Mir*[h], *Joshua J. Meeks*[i], *Kent W. Mouw*[j], *Marco Moschini*[k], *Andrea Necchi*[l], *Karima Oualla*[m], *Kamal S. Pohar*[n], *Jonathan E. Rosenberg*[o], *Bogdana Schmidt*[p], *Arlene O. Siefker-Radtke*[q], *Gary D. Steinberg*[r], *Arnulf Stenzl*[s], *Roger J. Buckley*[t], *Ashish M. Kamat*[u,*]

[a] *Department of Genitourinary Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH, USA;* [b] *Department of Genitourinary Oncology, Moffitt Cancer Center, Tampa, FL, USA;* [c] *Department of Urology, University of Kentucky, Lexington, KY, USA;* [d] *Department of Urology, Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA, USA;* [e] *Division of Hematology and Medical Oncology, Weill-Cornell Medicine, New York, NY, USA;* [f] *Fred Hutchinson Cancer Center, Department of Medicine, University of Washington, Seattle, WA, USA;* [g] *Department of Urology, Cambridge University Hospitals, Cambridge, UK;* [h] *Department of Urology, Hospital Universitario La Ribera, Valencia, Spain;* [i] *Department of Urology, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA;* [j] *Department of Radiation Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA;* [k] *Department of Urology, San Raffaele Hospital and Scientific Institute, Milan, Italy;* [l] *Department of Oncology, Vita-Salute San Raffaele University, Milan, Italy;* [m] *Department of Medical Oncology, Hassan II University Hospital, Fes, Morocco;* [n] *Department of Urology, Ohio State University, Columbus, OH, USA;* [o] *Genitourinary Oncology Service, Memorial Sloan Kettering Cancer Center, New York, NY, USA;* [p] *Department of Surgery, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA;* [q] *Department of Genitourinary Medical Oncology, MD Anderson Cancer Center, University of Texas, Houston, TX, USA;* [r] *Department of Urology, Rush University Medical Center, Chicago, IL, USA;* [s] *Department of Urology, Eberhard-Karls University, Tübingen, Germany;* [t] *Department of Urology, North York General Hospital, Toronto, Canada;* [u] *Department of Urology, MD Anderson Cancer Center, University of Texas, Houston, TX, USA*

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Abstract

Background and objective: The management of muscle-invasive bladder cancer (MIBC) is evolving rapidly with the emergence of new perioperative treatments and approaches for bladder preservation. We provide guidance on clinical staging and optimal therapeutic sequencing for patients with MIBC in clinical practice and within the context of clinical trial design.

Methods: The International Bladder Cancer Group (IBCG) convened global experts in bladder cancer to develop recommendations for the management of MIBC and to guide clinical trial design. Working groups reviewed the literature and developed draft recommendations. This was followed by voting by the IBCG members during a live meeting in August 2024 using a modified Delphi process. Recommendations achieving ≥75% agreement during the meeting were further refined and presented.

Key findings and limitations: The IBCG recommends thorough clinical staging and multidisciplinary care for patients with MIBC. Contemporary retrospective comparisons suggest that radical cystectomy (RC) and trimodal therapy have similar oncologic efficacy.

* Corresponding author. Department of Urology, MD Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, TX 77030, USA.
E-mail address: akamat@mdanderson.org (A.M. Kamat).

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Patients with pure squamous-cell carcinoma or adenocarcinoma are best managed with upfront RC, while cisplatin-based neoadjuvant therapy before RC is recommended for other histologic subtypes. Risk-stratified adjuvant therapy approaches should be used after RC. There are no currently validated predictive biomarkers to guide clinical decision-making in MIBC outside the context of a clinical trial. The IBCG recommends the use of time-to-event endpoints for perioperative therapy trials, and bladder-intact event-free survival for bladder preservation trials, with an emphasis on incorporating patient-reported quality-of-life endpoints.

Conclusions and clinical implications: The IBCG consensus recommendations provide practical guidance on optimal treatment sequencing strategies in the management of MIBC.

ADVANCING PRACTICE

What does this study add?

This consensus statement from the International Bladder Cancer Group provides updated, evidence-informed guidance on optimal treatment sequencing for muscle-invasive bladder cancer across neoadjuvant, adjuvant, bladder-preserving, and node-positive settings. The consensus integrates recent phase 3 data that have reshaped perioperative systemic therapy options, including immunotherapy-based and antibody-drug conjugate regimens. The recommendations emphasize multidisciplinary decision-making, appropriate patient selection, and consistent use of clinically meaningful time-to-event endpoints. The framework also highlights gaps in biomarker validation and quality-of-life assessment that should be addressed in future trials and clinical practice.

Clinical Relevance

Optimal management of muscle-invasive bladder cancer (MIBC) requires accurate staging, careful evaluation of comorbidities, and incorporation of patient priorities given the substantial effects of treatment on function, morbidity, and long-term quality of life. This consensus guidance emphasizes multidisciplinary care from diagnosis through treatment, outlining best practices in imaging and staging, contemporary selection and use of perioperative systemic therapy, and appropriate patient selection for bladder-sparing approaches. Recommendations are also provided for complex scenarios, including variant histology, locally advanced, and clinically node-positive disease. The statement further addresses the emerging role of biomarkers, including ctDNA, distinguishing clinical applications supported by evidence from investigational uses. Finally, it identifies key knowledge gaps—particularly the need for robust patient-reported outcomes—and proposes priorities for future clinical trial design in MIBC. Associate Editor: Sarah Psutka, MD.

Patient Summary

Experts from the International Bladder Cancer Group reviewed the best evidence available and expert opinions on how to treat muscle-invasive bladder cancer. We found that combining surgery or radiation with modern systemic treatments, chosen carefully for each patient, can improve outcomes. Decisions are best made by a multidisciplinary team and should also consider quality of life and patient preferences.

1. Introduction

The treatment landscape for advanced urothelial carcinoma (UC) has rapidly evolved with the emergence of checkpoint inhibitors, antibody-drug conjugates, and novel intravesical approaches for perioperative therapy and multimodal bladder preservation approaches in muscle-invasive bladder cancer (MIBC). Identification of optimum therapeutic sequencing and definition of appropriate clinical trial endpoints in MIBC are critical unmet needs for clinicians at the point of care and for industry and regulatory agencies in the context of clinical trial design.

2. Materials and methods

On August 22–23, 2024, during a live meeting of the International Bladder Cancer Group (IBCG), a global multidisciplinary steering committee of international experts in bladder cancer (urologists, medical oncologists, radiation oncologists, genitourinary pathologists, research scientists) and patient advocates was assembled to develop consensus recommendations on therapy sequencing in MIBC. Recommendations were based on literature evidence where possible, and clinical evidence where appropriate. Nonstructured literature searches in PubMed were performed by individ-

ual working groups, and publications were screened for inclusion in the evidence base. Working groups used a system that encompassed literature review, synthesis of expert opinion–based recommendation statements, open communication, and scientific debate. Specifically, panel members participated in a modified Delphi process. Recommendation statements were initially circulated via an online voting system for asynchronous pre-meeting voting by the IBCG membership.

During the live meeting, the different working groups presented results from the pre-meeting voting along with summarized evidence supporting the draft recommendations. Patient advocates were actively involved in audience participation and discussions in all the live meeting sessions. Their input was considered by the working groups as statements were iteratively refined, and patient advocates were included in final consensus voting. Recommendation statements were revised on the basis of feedback, and the final statements underwent further live voting (restricted to bladder cancer experts and patient advocates); consensus was defined as $\geq$75% agreement. These recommendations, which were refined via subsequent virtual conferences and discussions, form the basis of this manuscript. In a number of cases, when additional practice-changing data or clinical trial results became available in the time between the live meeting and manuscript submission, the authors considered and incorporated new evidence into the recommendations. All the authors reviewed, edited, and agreed on the final recommendations presented here.

3. Results

3.1. Setting the stage: contemporary outcomes of standard-of-care approaches for MIBC

The IBCG recommends that patients with newly-diagnosed MIBC should be offered referral to a multidisciplinary team consisting of urology, medical, and radiation oncology specialists in the decision-making process [1,2].

Cisplatin-based neoadjuvant chemotherapy (NAC) should be offered to eligible patients before cystectomy; alternative neoadjuvant approaches may be associated with higher pathologic complete response (pCR) rates, but these remain investigational.

Although prospective data are lacking, contemporary retrospective comparisons between radical cystectomy (RC) and trimodal therapy (TMT) suggest that they have similar oncologic efficacy in select patients with MIBC. Inability to deliver any portion of optimal cystectomy- or TMT-based therapy may compromise oncologic outcomes and should be factored in the decision-making process. Although an active area of promising investigation, there is currently no standard role for curative-intent MIBC treatment that omits definitive local therapy with either RC or radiation-based treatment in eligible patients.

Certain tumor genomic features (such as alterations in DNA repair genes or RNA-based molecular subtypes) are associated with prognosis following cystectomy and/or TMT treatment for MIBC, but currently lack sufficient prospective validation to guide clinical decision-making. There are no prospective data demonstrating a survival benefit from local therapy in patients with metastatic bladder cancer. Retrospective series suggest potential benefits from either cystectomy or radiation-based treatment, but are prone to selection and confounding biases and should be interpreted with caution, especially as the majority of the data are from the preimmunotherapy era [3,4]. Consolidative local therapy with either RC or radiation-based treatment can potentially be considered in selected patients with nodal or oligometastatic disease following a complete response to systemic therapy after thorough multidisciplinary review [5,6].

3.2. Clinical staging in MIBC

Contemporary staging for MIBC includes findings from transurethral resection of bladder tumor (TURBT) pathology, bimanual examination under anesthesia, and cross-sectional imaging of the chest, abdomen, and pelvis (computed tomography [CT] or magnetic resonance imaging [MRI]). Clinical staging is a dynamic process that can be re-evaluated throughout a patient's treatment course [7,8]. Abdominopelvic lymph nodes $\geq$10 mm in maximum short-axis diameter on CT or MRI should be considered suspicious for lymph node metastasis. Overall, current conventional imaging shows slight concordance (64.9%) between cN and pN stages (sensitivity 30%; specificity 84%) [9]. The IBCG recommends that staging CT or MRI should ideally be performed before TURBT to avoid surgery-related lymph node inflammation. In addition to size, nodal radiographic morphology should be taken into consideration when determining clinical nodal stage; factors such as rounded architecture, enhancement, and loss of a fatty hilum are associated with nodal metastasis.

Fluorodeoxyglucose (FDG) positron emission tomography (PET)-CT has limitations in staging bladder cancer because of high urinary excretion of FDG, which results in intense bladder activity that can obscure nearby tumors or lymph nodes. FDG PET-CT does not routinely improve initial clinical staging beyond conventional cross-sectional imaging; however, FDG PET/CT may inform treatment in specific clinical situations [10]. Such instances include staging of poorly differentiated neuroendocrine bladder tumors, which are frequently associated with atypical micrometastases; assessment of clinically suspicious pelvic nodes; and evaluation of other sites of concern that are difficult to biopsy. For patients with clinically positive pelvic nodes on conventional imaging, FDG PET-CT demonstrates pooled sensitivity of 52%, specificity of 92%, and accuracy of 81%, offering a slight improvement over the 76% accuracy seen with conventional staging alone [11,12].

While multiparametric MRI using the Vesical Imaging-Reporting and Data System (VI-RADS) scale exhibits favorable accuracy for primary tumor staging and may be useful for assessing primary tumor responses to systemic treatment, there was a lack of consensus that MRI should routinely be incorporated as a clinical staging modality. MRI is increasingly used in bladder cancer staging because of its high soft-tissue contrast, which aids in assessing the depth of tumor invasion. However, it is not yet fully established as a primary diagnostic tool in routine bladder cancer diagnosis.

MRI may have particular value in guiding organ-sparing decisions for female patients undergoing RC, although supporting evidence remains limited. Initial studies have shown that VI-RADS is both reliable and reproducible among radiologists, with good correlation to pathology findings [13]. Use of VI-RADS can potentially help in distinguishing between non–muscle-invasive bladder cancer (NMIBC) and MIBC [14]. Bladder MRI was also tested in the diagnostic setting in the BladderPath MRI trial; patients with suspected MIBC underwent multiparametric MRI to determine if immediate staging and treatment planning could replace traditional TURBT [15]. Results from this trial showed that an MRI-directed pathway can shorten the time to definitive treatment in comparison to the standard TURBT-based pathway but did not validate MRI as a reliable tool for distinguishing NMIBC from MIBC. Another limitation of this trial was the lack of pathologic assessment for patients before chemotherapy or radiotherapy. When bladder cancer is diagnosed, synchronous upper tract UC (UTUC) is found in approximately 2–4% of cases, and this incidence increases when high-grade or multifocal bladder tumors or cancer in situ are present. Owing to this risk, the IBCG recommends consideration of upper tract urography (CT urogram, MRI urogram, or retrograde pyelography) to identify patients with synchronous UTUC at the time of bladder cancer diagnosis, especially for high-risk cases [16]. The panel agreed that when there is a contraindication to iodinated contrast or gadolinium, retrograde pyelography combined with cross-sectional non-contrasted imaging suffices for UTUC evaluation.

The IBCG recommends that following neoadjuvant therapy, repeat clinical staging via cross-sectional imaging should be considered before consolidative surgery. Endoscopic evaluation of the primary tumor following neoadjuvant therapy can be considered for treatment planning. The majority of patients restaged with endoscopic evaluation and CT after cisplatin-based NAC and before cystectomy had no change or minimal changes in final treatment recommendations [17]. Moreover, endoscopic bladder assessment alone was unable to differentiate final pathologic stage in >50% of cases [18].

Lastly, emerging biomarkers such as circulating tumor DNA (ctDNA) and urinary tumor DNA are being explored as adjuncts to traditional staging and to assess the response to neoadjuvant systemic therapy [19].

3.3. *Neoadjuvant therapy in MIBC*

The IBCG recommends that cT2–4a N0 M0 MIBC is the appropriate clinical stage for defining a "neoadjuvant" cohort, and that patients diagnosed with MIBC should be offered inclusion in a clinical trial of perioperative therapy if one is accessible. The panel cautioned that chronologic age alone should not be part of the selection criteria for NAC use, and a thorough assessment of patient frailty is essential for guiding treatment decisions.

A calculated creatinine clearance (CrCl) value between 40 and 59 ml/min should not disqualify patients from receiving cisplatin-based NAC. CrCl has long been a key determinant in assessing eligibility for cisplatin-based chemotherapy in UC, with a historical threshold of CrCl $\geq$60 ml/min defined by Galsky et al. [20] for cisplatin eligibility. However, in real-world practice, clinicians frequently administer cisplatin in split doses to patients with CrCl in the range 40–59 ml/min [21,22]. In the NIAGARA trial (evaluating durvalumab and gemcitabine + cisplatin [GC] as neoadjuvant therapy), a lower CrCl cutoff of $\geq$40 ml/min was used for inclusion [23].

MIBC is a heterogeneous disease and treatment recommendations vary according to the presence of subtype histologies. While UC is the most common histology, several histologic subtypes exist that may influence treatment strategies. Patients with pure squamous-cell carcinoma or adenocarcinoma should be treated with upfront cystectomy [24]. Optimal neoadjuvant strategies remain undefined for patients with pure squamous-cell carcinoma or adenocarcinoma. Fit patients with MIBC with a subtype histology component (eg, micropapillary, plasmacytoid, nested, sarcomatoid) should be offered neoadjuvant therapy before RC in a multidisciplinary approach [24,25]. Contemporary clinical trials should strive to include patients with subtype histologies, even when these are predominant. For patients presenting with localized small-cell cancer of the bladder, NAC with etoposide + cisplatin should be offered, followed by RC or concurrent chemoradiotherapy with cisplatin [26].

In patients with presumed MIBC, maximal safe TURBT should be performed when possible. Maximal TURBT before cystectomy is associated with better pathologic downstaging, higher rates of pT0 status, and better long-term oncologic outcomes [27].

The IBCG recommends that for patients with MIBC who are fit for NAC, suitable therapeutic options are GC and dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin regimens [28,29]. More recently, the first perioperative immunotherapy-based regimen (GC + durvalumab) was approved by the US Food and Drug Administration (FDA) for MIBC on the basis of results from NIAGARA [23], a pivotal randomized phase 3 open-label trial that evaluated the efficacy of perioperative (neoadjuvant and adjuvant) durvalumab in combination with neoadjuvant GC versus neoadjuvant GC alone in a cohort of 1063 patients with MIBC. The primary endpoints were event-free survival (EFS) and the pCR rate; overall survival (OS) was a key secondary endpoint. Addition of perioperative durvalumab to neoadjuvant GC was associated with statistically significant improvements in EFS (hazard ratio [HR] 0.68, 95% [CI] 0.56–0.82; $p < 0.0001$) and OS (HR 0.75, 95% CI 0.59–0.93; $p = 0.0106$) in comparison to neoadjuvant GC alone [23]. Perioperative durvalumab and neoadjuvant GC is a regimen approved by the FDA and the European Medicines Agency for patients with MIBC who are fit for cisplatin, immunotherapy, and cystectomy.

For patients who are cisplatin-ineligible, there are no neoadjuvant treatment options recommended and upfront RC has been the standard. The phase 3 KEYNOTE-905/EV-303 trial compared the use of perioperative enfortumab vedotin and pembrolizumab (EV/P) versus surgery alone in 344 patients with MIBC who were ineligible for or refused cisplatin. Recent results revealed unprecedented outcomes: median EFS was not reached versus 15.7 mo (HR 0.40, 95% CI 0.28–0.57; $p < 0.0001$), and median overall

survival was not reached versus 41.7 mo (HR 0.50; 95% CI 0.33–0.74; $p = 0.0002$), which support EV/P as the new standard in this setting and mark a paradigm shift in this patient population [30]. This regimen is now approved by the FDA.

The IBCG panel recommends systemic therapy and repeat TURBT in patients with MIBC who are unwilling or unfit for both RC and radiation. The role of repeat TURBT in this setting is endorsed by the American Urological Association (AUA), as well for highly selected cases, particularly when a complete macroscopic resection is achievable and repeat TURBT confirms no residual disease, but should be considered only when other definitive treatments are not feasible [31].

3.4. Adjuvant therapy in MIBC

The IBCG panel recommends that adjuvant cisplatin-based chemotherapy should be offered to fit patients with MIBC who have pT3, pT4, or pN+ stage at cystectomy and did not receive prior NAC on the basis of a meta-analysis by the Advanced Bladder Cancer Meta-analysis Collaborators Group [32].

Among patients with MIBC who are unfit for (or refuse, despite adequate counseling) cisplatin, adjuvant nivolumab or pembrolizumab can be considered for those with pT3/4 and/or pN+ stage and for patients who have a residual muscle-invasive tumor (ypT2–4 and/or ypN+) after RC and before cisplatin-based NAC [33,34]. Both adjuvant nivolumab and pembrolizumab significantly prolonged disease-free survival (DFS) in comparison to placebo and observation, respectively, but no improvement in OS has been observed. The panel also recommends that if adjuvant cisplatin-based chemotherapy is given, there is no established role for a concurrent or sequential adjuvant checkpoint inhibitor. Patients who start neoadjuvant durvalumab with GC can continue durvalumab in the adjuvant setting according to the NIAGARA protocol design [23]. Given the recent approval of EV/P on the basis of results from the pivotal KEYNOTE-905 trial, patients who are cisplatin-ineligible or refuse cisplatin would be candidates for perioperative EV/P [30].

The IBCG recommends that ctDNA may be considered when making decisions about adjuvant checkpoint inhibitors for patients with high-risk MIBC. Prospective data from the phase 3 IMvigor011 trial demonstrated that for patients with high-risk MIBC who remained or converted to ctDNA-positive within 12 mo after RC, adjuvant atezolizumab significantly improved DFS and OS in comparison to placebo, and thus offer the first level 1 evidence for a molecular residual-disease–guided strategy for adjuvant immunotherapy [35]. In addition, extended 5-yr follow-up data and an exploratory analysis for the phase 3 CheckMate 274 trial of adjuvant nivolumab in patients with high-risk MIBC following RC similarly showed a disease-specific survival advantage exclusively for patients with ctDNA positivity after surgery [36]. Serial ctDNA testing may help in refining patient selection for adjuvant therapy by identifying those who are likely to benefit from immunotherapy while sparing individuals who are persistently ctDNA-negative from unnecessary treatment.

There is currently no evidence to support checkpoint inhibitor rechallenge after prior immunotherapy in MIBC. The IBCG recommends that if anti-PD1/L1 therapy is used in the perioperative setting, the role of rechallenge at the time of cancer progression is unclear and requires a balanced discussion of risks versus benefits and careful consideration of the time of cancer progression in relation to PD1/L1 inhibitor administration, tolerance, and patient preferences, among other factors.

3.5. Multidisciplinary management of lymph node metastasis

The IBCG recognizes that the classification of locally advanced bladder cancer (laBC) remains controversial because of overlapping definitions, differences in staging paradigms, and variability in clinical trial inclusion criteria. Traditionally, laBC has been defined as cT4b and/or node-positive (any N+) disease without distant metastasis (M0). However, some clinical trials extend the definition to include M1a (nonregional lymph node metastases), especially in the context of consolidative or multimodal therapy discussions. The 8th edition of the American Joint Committee on Cancer staging manual classifies stages IIIA (T3–T4a, N0, M0), IIIB (any T, N1–N3, M0), and IVA (T4b, any N, M0; or any T, any N, M1a) as laBC, which encompasses invasion into adjacent organs or regional/nonregional lymph node involvement without distant organ spread [37]. The AUA guidelines for MIBC do not define laBC, but consider T3–T4 and/or N+ disease as "high-risk" requiring a multidisciplinary approach [31]. These differences in definition underscore the need for nuanced treatment planning and consistent staging nomenclature in both clinical practice and clinical trial eligibility criteria. The IBCG panel did not reach consensus on inclusion of M1a in the definition of laBC.

When treated with combination systemic therapy, patients with oligometastatic pelvic nodal involvement from MIBC have favorable prognosis in comparison to metastases at other distant sites. A post hoc analysis for CheckMate 901 showed that 18% of the patients enrolled had lymph node–only metastases, and this group had a higher response rate with GC and nivolumab in comparison to those who received GC only; the HR for OS (0.58) favored the GC + nivolumab combination [38]. Results from the pivotal EV-302 trial showed that EV/P resulted in significantly better response rates, PFS, and OS across all subgroups in comparison to platinum-based chemotherapy; the HR for OS was 0.45 in the subgroup with nodal metastases [39]. In the Javelin Bladder 100 trial, patients with nodal metastases also had the most favorable outcomes over longer follow-up; the HR for OS was 0.86 in the group that received switch maintenance avelumab and best supportive care (BSC) in comparison to BSC alone [40]. When available and feasible, EV/P should be offered as the preferred regimen for locally advanced or metastatic UC, regardless of sites of metastases, the site of the primary tumor, or cisplatin eligibility [41].

Radical local treatment with RC and lymph node dissection or TMT could be considered for patients with de novo oligometastatic nodal involvement who have experienced a sustained complete response to systemic therapy in the

context of careful expert multidisciplinary management, but this is currently not a standard recommendation.

FDG PET use can be considered in selected patients, but is not routinely recommended. Systemic recurrence following initial therapy for MIBC is frequent, which suggests that better pretreatment clinical staging is necessary. FDG PET might be considered in selected patients, as a retrospective analysis found that it led to a change in management for18% of patients with MIBC [10]. Patients at higher risk of upstaging are those with cT3–4 and/or N+ disease. FDG PET might be helpful in cases with suspicious lymph node metastases on conventional imaging, and previous treatment with neoadjuvant therapy does not seem to be a contraindication.

Multidisciplinary management and general principles for response and surgical/radiotherapy consolidation may include:

(a) Absence of pelvic side-wall invasion on imaging and/or examination under anesthesia (goal is R0 resection in surgical candidates);
(b) Complete resolution of lymph nodes according to imaging or biopsy negative for residual disease; and
(c) A period of disease stability without progression elsewhere.

The optimal timing in patients with no complete response and a period of stability without progression should be discussed carefully in an expert multidisciplinary setting. Oligometastatic disease may offer an opportunity for multidisciplinary management of metastasis-directed therapy (surgical or radiation) in well-selected patients. Radiation should be considered in both surgical candidates and those who do not wish to consider, or are not candidates for, surgery.

3.6. Biomarkers for patient selection

Current biomarkers do not inform decisions on NAC in patients with MIBC who are eligible for cisplatin. Therefore, all decisions on neoadjuvant/adjuvant therapy selection should be based on clinical characteristics such as comorbidities, clinical stage, pathology, and imaging results, among other factors. Shared informed decision-making between clinicians and patients remains essential, particularly without reliable molecular biomarker data. Research on biomarkers to predict responses to systemic therapies is warranted for patients with MIBC. Predictive biomarkers need to be validated in prospective clinical trials before they are used to guide clinical decision-making outside clinical trials.

Efforts to identify RNA- and DNA-based biomarkers for predicting responses to systemic therapies have not resulted in validated clinical biomarkers. Despite promising avenues of research, no biomarker has demonstrated adequate predictive value for adoption in routine clinical practice. However, the perioperative setting offers a unique opportunity to collect and evaluate biomarkers from tissue, blood, and urine, both before and after treatment, which may provide critical insights for future research.

In the adjuvant setting, the role of biomarkers is becoming more important. For example, CheckMate 274 demonstrated a greater DFS benefit from adjuvant nivolumab in the group of patients who had tumors with PDL1 expression $\geq$1% (HR 0.56, 95% CI 0.36–0.86) [42]. While this suggests that PDL1 status may possibly help in identifying patients who are more likely to benefit from nivolumab, it should not serve as the sole criterion for patient selection, as benefit can also occur in patients with lower PDL1 expression.

ctDNA is another very promising biomarker under investigation, especially in the adjuvant setting. Detectable ctDNA after cystectomy for MIBC may indicate higher risk of recurrence and a potential benefit from adjuvant therapy. However, such research should be conducted within clinical trials. For instance, an exploratory subset analysis for the IMvigor010 trial revealed significantly better DFS and OS for ctDNA-positive patients treated with atezolizumab, while those who were ctDNA-negative did not experience a significant benefit [43]. While ctDNA testing is not yet standard in clinical practice, a recent press release from the IMvigor011 trial reported that patients with ctDNA^{+} status had better OS and DFS with atezolizumab in comparison to placebo [44]. There are also emerging opportunities for investigating urinary cell-free DNA as a predictive biomarker (and for assessment of therapy response) in the perioperative setting.

Until emerging biomarkers are validated and standardized across different practice settings, decisions regarding neoadjuvant/adjuvant therapy selection should prioritize clinical parameters. Integration of biomarker research in well-designed clinical trials remains critical for advancing personalized approaches in MIBC treatment and understanding disease biology.

3.7. Trial design and appropriate endpoints

Trials of perioperative systemic therapy should include patients with surgically resectable disease (cT2–4a N0–1 M0, or cT1–4a N1 M0) who are eligible for systemic therapy, RC, and pelvic lymph node dissection. Ongoing phase 3 trials (eg, Keynote 866, ENERGIZE, Keynote B15, Keynote 905, and VOLGA) include patient populations with localized resectable MIBC. Ensuring similar/harmonized populations and key eligibility parameters across these large trials may allow easier interpretation of results and coordinated discussion within a relevant context/framework for the totality of the data available. Inclusion of cN1 disease (a single enlarged perivesical lymph node) seems reasonable according to consensus, and recognizing the challenge in accurate clinical staging and common scenarios in borderline sizes for single lymph nodes.

Trials in cT_{any} N2–3 M0 disease may consider data-driven systemic therapy followed by consolidative locoregional therapy. Evaluation, ideally in a multidisciplinary setting, must be customized to each case with consideration of the following care pathways:

(a) Continuation of systemic therapy with dose adjustments as needed, depending on toxicity, the depth and duration of any response, patient preferences, the therapy burden, and provider expertise, among other factors;
(b) Potential consolidative locoregional therapy (based on the depth and duration of response), which may include extirpative surgery or (chemo)radiation; and
(c) Close surveillance.

There is a lack of prospective data delineating the optimal duration of systemic therapy in the locoregionally advanced disease setting. Subgroup analyses for the EV-302, Checkmate 901, and Javelin Bladder 100 trials showed that patients with lymph node–only metastasis have better prognosis than patients with bone and/or visceral metastasis (regardless of systemic therapy used). Dose adjustments are based mainly on toxicity and the therapy burden, while data from EV-302 trial can further help to inform relevant decision-making [38–40]. The role of consolidation therapy with either extirpative surgery or (chemo) radiation remains experimental and should be evaluated in prospective clinical trials. In the interim, retrospective data, with acknowledgment of their inherent limitations and caveats, may help to inform the discussion and might influence informed shared decision-making after multidisciplinary review.

Unless driven by a robust biological rationale for exclusion (eg, neuroendocrine cancer), the inclusion of subtype histologies in trials in localized MIBC is recommended and may (ideally) not mandate predominant conventional UC histology. The presence of histologic subtypes may serve as a stratification factor for predefined subgroup analyses. The NIAGARA trial included patients with primary UC, while most trials mandate predominant conventional UC histology [23]. Our consensus on the basis of discussion with expert pathologists is to allow any percentage of subtype histology if the primary tumor is UC, while recognizing the major challenge in accurately estimating such a percentage, inherent spatial tumor heterogeneity, and the need for broader inclusion of patients to generate relevant data. Clinical trials focusing mainly on histologic subtypes are also very important and should be strongly encouraged.

Pathology review of TURBT and cystectomy specimens by a pathologist with expertise in bladder cancer is strongly recommended, as interpretation can impact staging, identification of histologic subtypes, clinical trial eligibility, and endpoints. Expert pathology and radiology review have an impact on multidisciplinary decision-making [45,46].

Appropriate primary endpoints for MIBC trials should be tailored to the treatment modality used:

(a) For randomized phase 2–3 trials, a time-to-event primary endpoint is essential.
(b) Bladder-intact EFS is the primary endpoint recommended for randomized trials of TMT or other bladder preservation approaches [47].
(c) For randomized trials evaluating neoadjuvant (± adjuvant therapy), EFS is the primary endpoint recommended.
(d) For randomized trials evaluating adjuvant therapy, DFS should be the primary endpoint.
(e) OS should be captured, at least as a key secondary endpoint, in all such trials.

pCR (ypT0 N0) is an appropriate primary endpoint for single-arm "signal-seeking" trials in the neoadjuvant setting; pathologic downstaging (<ypT2N0) should be captured as a key secondary endpoint. However, there may be some confounding factors around the use of pCR as a primary endpoint. TURBT before neoadjuvant therapy may remove all visible disease, which could possibly inflate the pCR rate. Inadequate imaging or understaging (especially in cT1/T2 disease) may lead to overestimation of the treatment effect. In addition, variability in pathology evaluation may introduce inconsistencies in pCR classification. Notably, in the NIAGARA trial, the combination of neoadjuvant GC with durvalumab resulted in a relatively moderate improvement in the pCR rate vs GC, but showed a significant improvement in EFS and OS [23]. Accurate characterization of a clinical complete response (cCR) to neoadjuvant or induction systemic therapy is constrained by the limitations of contemporary methods for clinical staging. The cCR description should be driven by studies that have used a prespecified detailed definition of cCR (eg, negative tissue biopsy, urine cytology, cross-sectional imaging) and evaluated its association with relevant clinical outcomes, such as time-to-event endpoints. A uniform standardized definition of post-NAC cCR is currently lacking [48]. A consensus-driven definition of endpoints for next-generation bladder-sparing perioperative trials has been proposed [49].

3.8. *Quality-of-life endpoints, frailty, and recovery*

The IBCG recommends that patient-reported quality of life (QoL) outcomes should be key endpoints in prospective interventions and trials and should include assessments at baseline, during treatment, and after treatment completion. When making treatment decisions, patients increasingly prioritize discussions about QoL. This is particularly important given the modest survival benefits of many regimens, especially in advanced disease. Thus, the impact of interventions on patient wellbeing should be measured [50]. In a review of 149 high-impact oncology trials, only 3% reported QoL outcomes up until each patient's death. Most assessed QoL during or shortly after the intervention, with few extending measurements to the end of life. Of those that did, 80% found worse QoL outcomes in the intervention group, despite this being a priority for patients [51]. Use of validated assessments of patient frailty, multimorbidity, and functional status should be considered before surgery and bladder preservation strategies to improve informed shared decision-making.

Frailty is associated with higher complication and mortality rates from RC and there is a need for accurate identification of frailty to inform risk assessment and support shared decision-making [52]. Although comprehensive multidisciplinary assessments with geriatricians are not always clinically feasible, the 11-item Modified Frailty Index, which has been well studied in the cystectomy setting, offers a practical alternative. This validated tool can be used to help in counseling patients on complication and mortality rates [53]. A prehabilitation program with nutrition and exercise counseling, if available, should be recommended to all patients before surgery and/or systemic therapy, especially frail and/or comorbid patients [54].

A multidisciplinary, multimodal prehabilitation trial involving 70 patients scheduled for RC demonstrated better 4-wk functional capacity in the intervention group [55]. While this study had significant loss to follow-up, numer-

ous ongoing trials evaluating telerehabilitation platforms may make this approach more feasible globally.

Enhanced recovery after surgery (ERAS) is an important treatment component for patients undergoing RC. A meta-analysis of 4048 patients showed that implementation of ERAS protocols was associated with shorter length of stay and lower postoperative complication rates [56]. Various ERAS protocols for RC have been published, each differing in the number and type of components included [57]. Further investigation is needed to better understand which specific ERAS elements are most beneficial for patients undergoing RC. At present, non-opioid analgesia and avoidance of a nasogastric tube appear to reduce length of stay [56].

Given the adverse effects of opioid analgesia, multimodal non-opioid pain management options, such as NSAIDs, neuropathic agents, such as gabapentin/pregabalin, and local blocks should be prioritized in postoperative pain pathways. It has been shown that opioid-free pain relief, both intraoperatively and postoperatively, is feasible for cystectomy [58].

4. Discussion

The consensus recommendations from the IBCG are based on literature evidence and clinical expert opinion and are summarized in Table 1.

Table 1 – International Bladder Cancer Group consensus recommendations on clinical management and clinical trial design in MIBC

Contemporary standard-of-care approaches

1. Patients with newly diagnosed MIBC should be offered referral to a multidisciplinary team consisting of urologic, medical, and radiation oncology specialists.
2. Cisplatin-based NAC should be offered to eligible patients before RC. Cisplatin-ineligible patients should be treated with neoadjuvant enfortumab vedotin and pembrolizumab.
3. Although prospective data are lacking, contemporary retrospective comparisons between RC and TMT suggest similar oncologic efficacy in selected patients with MIBC.
4. Inability to deliver any portion of optimal RC- or TMT-based therapy may compromise oncologic outcomes and should be factored in the decision-making process.
5. Although an active area of investigation, there is currently no standard role for curative-intent MIBC treatment that omits definitive local therapy with either RC or radiation-based treatment in eligible patients.
6. Certain tumor genomic features (such as alterations in DNA repair genes or RNA-based molecular subtypes) are associated with prognosis following RC- and/or TMT-based treatment for MIBC but currently lack sufficient prospective validation to guide clinical decision-making.
7. Consolidative local therapy with either RC or radiation-based treatment can potentially be considered in selected patients with nodal or oligometastatic disease following complete response to systemic therapy after thorough multidisciplinary review.

Clinical staging in MIBC

1. Contemporary staging for MIBC includes findings from TURBT pathology, bimanual examination under anesthesia, and cross-sectional imaging of the chest, abdomen, and pelvis (CT or MRI). Clinical staging is a dynamic process that can be re-evaluated throughout a patient's treatment course.
2. Abdominopelvic lymph nodes $\geq$10 mm in maximum short-axis diameter, detected on CT or MRI, should be considered suspicious for lymph node metastasis.
3. FDG PET/CT does not routinely improve initial clinical staging beyond conventional cross-sectional imaging; however, in specific clinical situations, FDG PET/CT may inform treatment.
4. Upper tract urography (CT urogram, MRI urogram, or retrograde pyelography) should be considered to exclude patients with synchronous upper tract urothelial cancer.
5. Following neoadjuvant therapy, repeat clinical staging via cross-sectional imaging should be considered before consolidative surgery. Endoscopic evaluation of the primary tumor following neoadjuvant therapy can be considered for treatment planning.
6. Emerging biomarkers, such as ctDNA and urinary tumor DNA, are being explored as adjuncts to traditional staging to assess the response to neoadjuvant therapy.

Neoadjuvant therapy

1. cT2–4a N0 M0 MIBC is the appropriate clinical stage for defining a "neoadjuvant" cohort.
2. Patients diagnosed with MIBC should be offered inclusion in a clinical trial of perioperative therapy if one is accessible.
3. Chronologic age alone should not be part of the selection criteria for NAC; a more comprehensive assessment of patient frailty is needed.
4. Estimated glomerular filtration rate between 40 and 59 ml/min (eg, using the Cockcroft-Gault formula) should not disqualify patients from receiving cisplatin-based NAC.
5. Patients with pure squamous-cell carcinoma or adenocarcinoma should be treated with upfront surgery. Patients with muscle-invasive urothelial carcinoma with subtype histology components should be offered neoadjuvant therapy before RC on the basis of multidisciplinary care.
6. In patients with presumed MIBC, maximal safe TURBT should be performed when possible.
7. In patients with MIBC who are fit for NAC, GC and dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin regimens are suitable therapeutic options.
8. Systemic therapy and repeat TURBT are recommended for patients with MIBC who are unwilling or unfit for both RC and radical radiotherapy.

Adjuvant therapy

1. Adjuvant cisplatin-based chemotherapy should be offered to fit patients with MIBC who have pT3, pT4, or pN+ stage at RC and did not receive prior cisplatin-based NAC.
2. Adjuvant nivolumab or pembrolizumab can be considered for cisplatin-unfit patients (or those who refuse despite adequate counseling) with MIBC with pT3/4 and/or pN+ stage or who have a residual muscle-invasive tumor (ypT2–4 and/or ypN+) after RC and prior cisplatin-based NAC.
3. If adjuvant cisplatin-based chemotherapy is given, there is no established role for concurrent or sequential adjuvant anti-PD1/L1 therapy.
4. ctDNA may be considered when making decisions about adjuvant immunotherapy for patients with high-risk MIBC. However, additional research is needed to prove clinical utility before this is standard of care.
5. If anti-PD1/L1 therapy is used in the neoadjuvant and/or adjuvant setting, the role of rechallenge at the time of progression is unclear and requires a balanced discussion of the risks versus benefits and careful consideration of the time of cancer progression in relation to anti-PD1/L1 administration, tolerance, and patient preferences, among other factors.

Table 1 – *Continued*

Multidisciplinary management of metastatic disease

1. Patients with oligometastatic pelvic nodal involvement from MIBC have favorable prognosis in comparison to other metastatic sites when treated with combination systemic therapy.
2. The use of FDG PET can be considered in selected patients, but is not routinely recommended.
3. When available, enfortumab vedotin + pembrolizumab is the treatment of choice for untreated locally advanced and metastatic bladder cancer. However, there are still no comparison data versus GC + nivolumab, or cisplatin followed by a maintenance regimen.
4. Radical local treatment with RC and lymph node dissection or TMT could be carefully considered in cases with de novo oligometastatic nodal involvement if the patient has a sustained complete response to systemic therapy in the context of careful expert multidisciplinary management, although this is currently not a standard recommendation.
5. Multidisciplinary management is essential in identifying disease response and resectability. General principles for response and surgical consolidation may include:

a. The absence of pelvic side-wall invasion on imaging and/or EUA (goal is R0 resection in surgical candidates);
b. Complete resolution of lymph nodes according to imaging or negative biopsy for residual disease; and
c. A period of disease stability without progression elsewhere.

6. Oligometastatic disease offers an opportunity for multidisciplinary management of metastasis-directed therapy (surgical or radiation).

Biomarkers for patient selection

1. Current biomarkers do not inform decisions on NAC for patients with MIBC who are eligible for cisplatin.
2. Research on biomarkers to predict response to systemic therapies is warranted for patients with MIBC. Predictive biomarkers may be standardized and incorporated to guide clinical decision-making outside of clinical trials.
3. PD-L1 testing may help in identifying patients who are more likely to benefit from adjuvant nivolumab, but it should not be the sole criterion for patient selection.
4. Detectable ctDNA after RC for MIBC may indicate a higher risk of recurrence and potential benefit from adjuvant therapy.
5. Until emerging biomarkers are validated and standardized across different practice settings, decisions regarding neoadjuvant/adjuvant therapy selection should prioritize clinical parameters.

Trial design and appropriate endpoints

1. Trials of preoperative systemic therapy should include patients with surgically resectable disease (cT2–4a N0–1 M0) eligible for systemic therapy, RC, and pelvic lymph node dissection.
2. Trials in patients with cT_{any} N2–3 M0 disease may consider data-driven systemic therapy followed by consolidative locoregional therapy, which may include extirpative surgery or (chemo)radiation.
3. Unless driven by a robust biological rationale for exclusion, the inclusion of histologic subtypes in trials in localized MIBC is recommended, and predominant conventional urothelial histology may (ideally) not be required. The presence of a histologic subtype may serve as a stratification factor and be included in predefined subgroup analyses.
4. Pathology review of TURBT and cystectomy specimens by a pathologist with expertise in bladder cancer is strongly recommended, as interpretation can impact staging, identification of histology subtypes, clinical trial eligibility, and endpoints.
5. Appropriate primary endpoints for MIBC trials should be tailored to the treatment modality used:

a. For randomized phase 2–3 trials, a time-to-event primary endpoint is essential.
b. Bladder-intact event-free survival is the primary endpoint recommended for randomized trials of TMT or other bladder preservation approaches.
c. For randomized trials evaluating neoadjuvant (with/without adjuvant therapy), event-free survival is the primary endpoint recommended.
d. For randomized trials evaluating adjuvant therapy, disease-free survival should be the primary endpoint.
e. Overall survival should be captured at least as a key secondary endpoint in all such trials.

6. pCR (ypT0 N0) is an appropriate primary endpoint for single-arm "signal seeking" trials in the neoadjuvant setting; pathologic downstaging (<ypT2 N0) should be captured as a secondary endpoint. Note that pCR can be confounded by the completeness and extent of TURBT procedures.
7. Accurate characterization of a cCR to neoadjuvant/induction systemic therapy is constrained by the limitations of contemporary clinical staging methods. Description of cCR should be driven by studies that used a prespecified detailed definition of cCR (eg, negative tissue biopsy, cytology, cross-sectional imaging) and evaluated its association with relevant clinical outcomes (such as time-to-event endpoints).

QoL endpoints, frailty, and recovery

1. Patient-reported QoL outcomes should be key endpoints in prospective interventions/trials and should include assessments at baseline, during treatment, and following treatment completion.
2. Use of validated assessments of patient frailty, multimorbidity, and functional status should be considered perioperatively to improve shared decision making.
3. A prehabilitation program with nutrition and exercise counseling, if available, should be recommended to all patients before surgery and/or systemic therapy, especially in frail and/or comorbid patients.
4. ERAS is an important treatment component for patients undergoing RC. Further investigation is needed to better understand which specific ERAS elements are most beneficial in the RC setting.
5. Given the adverse effects of opioid analgesia, multimodal non-opioid options for pain management such as NSAIDs, neuropathic agents (eg, gabapentin or pregabalin), and local blocks should be prioritized in postoperative pain pathways.

cCR = clinical complete response; CT = computed tomography; ctDNA = circulating tumor DNA; ERAS = enhanced recovery after surgery; EUA = examination under anesthesia; FDG = fluorodeoxyglucose; GC = gemcitabine + cisplatin; MIBC = muscle-invasive bladder cancer; MRI = magnetic resonance imaging; NAC = neoadjuvant chemotherapy; NSAID = nonsteroidal anti-inflammatory drug; pCR = pathologic complete response; PET = positron emission tomography; QoL = quality of life; RC = radical cystectomy; TMT = trimodal therapy; TURBT = transurethral resection of bladder tumor.

This consensus provides updated, evidence-informed guidance for multidisciplinary management of MIBC and laBC, with a focus on optimal staging, perioperative therapies, systemic treatment strategies for node-positive disease, biomarkers, trial design, and QoL considerations.

5. Conclusions

As the therapeutic landscape for MIBC and laBC is rapidly evolving, the aim of this IBCG framework is to guide clinicians, researchers, and other stakeholders in delivering

and supporting optimized patient-centered care and generating high-quality evidence.

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