INTERNATIONAL
BLADDER CANCER
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International Bladder Cancer Group

Newsletter



Volume 1
2026

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INTERNATIONAL BLADDER CANCER GROUP

Index

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Articles

1. Society of Urologic Oncology (SUO) 2025

2. ASCO Genitourinary Cancer Symposium 2026: Highlights

3. EAU 2026 Bladder Cancer Highlights

4. Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates

5. Bladder Preservation in Muscle Invasive Bladder Cancer Current Trials and Future Directions

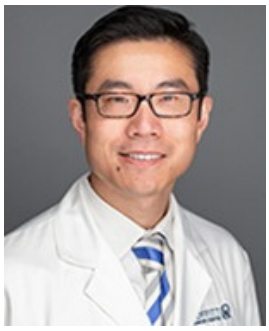
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Society of Urologic Oncology (SUO) 2025



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The 26th annual meeting of the Society of Urologic Oncology was held from December 2-5, 2025, in Phoenix, Arizona. Bladder sessions spanned the spectrum of bladder cancer management, from hematuria guidelines to management following clinical complete response in the metastatic urothelial setting. Additionally, the session featured a comprehensive review of newly emerging trials in the intermediate risk non-muscle invasive bladder cancer space, including a debate immediately preceding this overview regarding use of traditional AUA NMIBC risk- stratification schema versus the IBCG risk factor group schema developed by this organization.

The phase 3 KEYNOTE-905/EV-303 trial evaluated perioperative enfortumab vedotin (EV) plus pembrolizumab in cisplatin-ineligible or cisplatin-declining patients with muscle-invasive bladder cancer. Patients were randomized to neoadjuvant and adjuvant EV+pembrolizumab plus radical cystectomy versus surgery alone. Among 344 patients, more than 87% underwent surgery. EV+pembro significantly improved event-free survival (HR 0.40; median not reached), overall survival (HR 0.50), and pathologic complete response rates (57.1% vs. 8.6%) compared with surgery alone. While adverse events were more frequent with combination therapy, safety was consistent with known profiles. These findings establish EV+pembrolizumab as the first perioperative regimen to demonstrate clear benefit in cisplatin-ineligible MIBC and support its adoption as a new standard of care.

While numerous international guidelines exist—such as those of the AUA, EAU, NCCN, and IBCG—most are broadly concordant, differing mainly in nuance. The goal of this project was **not to reinvent new guidelines**, but rather to **integrate the best elements of existing ones**, updated with the latest evidence, into a **clear, practical, and resource-sensitive framework** reflecting Mexico's healthcare systems.

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Society of Urologic Oncology (SUO) 2025



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IMvigor011 is a randomized, double-blind phase III trial evaluating a circulating tumor DNA (ctDNA)-guided adjuvant strategy in patients with high-risk muscle-invasive bladder cancer after radical cystectomy. Patients underwent serial ctDNA surveillance, and those who became ctDNA-positive without radiographic recurrence were randomized 2:1 to receive adjuvant atezolizumab or placebo, while ctDNA-negative patients continued observation. Exploratory subgroup analyses were presented at SUO 2025. Among 761 patients enrolled in the surveillance arm, surgical staging alone could not reliably predict molecular residual disease. In the ctDNA-positive cohort, adjuvant atezolizumab significantly improved disease-free and overall survival compared with placebo, with consistent benefit across tumor stages, nodal status, and prior neoadjuvant chemotherapy. Conversely, patients who remained ctDNA-negative had uniformly favorable outcomes without adjuvant therapy irrespective of clinical or pathological factors. These findings reinforce ctDNA-based minimal residual disease (MRD) testing as a powerful tool to refine postoperative risk stratification and selectively identify patients most likely to benefit from adjuvant immunotherapy while avoiding overtreatment in those who are ctDNA-negative.

The first results from the Phase 2 CORE-008 trial show that intravesical cretostimogene grenadenorepvec demonstrates compelling activity and excellent tolerability in patients with high-risk, BCG-naïve non–muscle-invasive bladder cancer. Among 54 treated patients—most with CIS-containing disease—49 were evaluable, and the complete response rate reached 83.7%. There were no cases of progression to muscle-invasive or metastatic disease. Treatment was well tolerated, with adverse events primarily low grade, localized to the bladder. There were no serious treatment-related adverse events or treatment discontinuations. These early findings highlight cretostimogene's potential as an effective, single-agent intravesical therapeutic option for BCG-naïve HR-NMIBC and support its continued development across disease states.

Finally, the late breaking abstract session featured two readouts in the BCG unresponsive papillary-only (Ta/T1) disease space.

Results from Cohort P in the BOND-003 trial provides promising early evidence that intravesical cretostimogene grenadenorepvec may offer an effective, bladder-sparing option for patients with papillary-only BCG-unresponsive NMIBC. In this single-arm study of 56 evaluable patients, high-grade recurrence-free survival rates were 84.6% at 6 months and 80.4% at 9 months, with no patients requiring cystectomy at the time of data cutoff. Treatment was well tolerated, with predominantly low-grade, bladder-localized adverse events or no treatment-related serious events, discontinuations, or dose delays.

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Society of Urologic Oncology (SUO) 2025

The SunRISe-1 Cohort 4 study reports encouraging 1-year efficacy and safety results for TAR-200, a sustained-release intravesical gemcitabine system, in patients with BCG-unresponsive papillary-only NMIBC. Among 52 treated patients, the 12-month disease-free survival rate was 74.3%, with similar outcomes in both high-grade Ta and T1 subgroups. Overall and progression-free survival rates were 98% and 95.6%, respectively. TAR-200 was generally well tolerated, with most adverse events being low-grade urinary symptoms and few treatment discontinuations. Patient-reported quality-of-life measures, including global health status and physical functioning, remained stable throughout treatment.

These findings support both TAR-200 and cretostimogene as promising therapeutic options for bladder preservation in BCG-unresponsive papillary-only NMIBC. Notably, there has been a recent NCCN Guideline adoptions as Category 2b recommendations for several novel intravesical therapy agents in the papillary-only disease space. It remains unclear where we are heading with papillary-only BCG unresponsive disease, as the FDA has made their stance clear that label approval requires prospective randomized trials due to the confounding effects of radical transurethral resection in papillary disease. In the meantime, exploratory cohorts of papillary-only patients in single-arm trials designed for registration purposed in patients with BCG unresponsive CIS provide proof of principle.

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ASCO Genitourinary Cancer Symposium 2026: Highlights



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Introduction

The genitourinary-oncology world recently convened in San Francisco, California in the United States from February 26-28th for the annual 2026 ASCO Genitourinary Cancers Symposium. The second day of the symposium focused on bladder and urothelial carcinoma with practice changing data presented from the KEYNOTE-B15/EV-304 study, pivotal information from the NIAGRA study on the role of utDNA, and intriguing data from SWOG S1602 on the use of the Tokyo BCG strain and priming in treatment of NMIBC.

KEYNOTE-B15/EV-304: EV + Pembrolizumab Outperforms Cisplatin-Based Chemotherapy in Cisplatin-Eligible MIBC

One of the most anticipated presentations at ASCO GU 2026 was the first reporting of the KEYNOTE-B15/EV-304 trial (NCT04700124), presented by Dr. Galsky of Mount Sinai1. This randomized, open-label phase III trial compared perioperative enfortumab vedotin (EV) plus pembrolizumab (EV+P) versus neoadjuvant cisplatin plus gemcitabine followed by radical cystectomy with pelvic lymph node dissection (RC + PLND) in 808 cisplatin-eligible patients with MIBC.

The results were striking across all three co-primary and key secondary endpoints. EV+P demonstrated a statistically significant and clinically meaningful improvement in event-free survival (EFS), with a hazard ratio of 0.53 (95% CI 0.41–0.70, $p<0.0001$). The 12-month EFS was 86.0% versus 75.4%, and the 24-month EFS was 79.4% versus 66.2% in favor of EV+P. Median EFS in the chemotherapy arm was 48.5 months and had not been reached in the EV+P arm at data cutoff. Overall survival also favored EV+P, with a hazard ratio of 0.65 (95% CI 0.48–0.89, $p=0.0029$). Two-year OS rates were 93.1% and 89.6% in the EV+P and chemotherapy arms, respectively.

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ASCO Genitourinary Cancer Symposium 2026: Highlights



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The pathological complete response (pCR) rate (pT0N0) after cystectomy was 55.8% with EV+P compared to 32.5% with chemotherapy, representing an estimated absolute difference of 23.4% (p<0.0001). Among patients who actually underwent surgery, pCR rates were 64.4% and 36.3%, respectively. Efficacy benefits were consistent across all evaluated subgroups including age, sex, PD-L1 status, and tumor stage.

Surgical feasibility was not compromised based on neoadjuvant therapy, with rates of completed resection being similar between the two arms (346/351 vs. 352/361). The safety profile was consistent with prior experience with EV+P in the advanced/metastatic urothelial carcinoma setting. Grade ≥3 treatment-emergent adverse events occurred in 75.7% of EV+P patients versus 67.2% in the chemotherapy arm, with the EV+P arm reporting a longer treatment exposure window that encompasses both neoadjuvant and adjuvant phases.

Together with results from KEYNOTE-905/EV-303 in cisplatin-ineligible patients, KEYNOTE-B15 establishes perioperative EV plus pembrolizumab as a novel standard of care option for patients with MIBC regardless of cisplatin eligibility. This represents the first time an antibody-drug conjugate combined with an immune checkpoint inhibitor has demonstrated superiority over cisplatin-based chemotherapy in this curative-intent population.

NIAGARA Biomarker Analysis: Urinary Tumor DNA Offers Complementary Insights to Circulating Tumor DNA

Presented by Dr. Michiel Van der Heijden of the Netherlands Cancer Institute, this exploratory analysis from the landmark NIAGARA trial evaluated the utility of urinary tumor DNA (utDNA) in combination with plasma circulating tumor DNA (ctDNA) as a biomarker in perioperatively treated MIBC patients2. The NIAGARA trial itself previously demonstrated that perioperative durvalumab added to neoadjuvant gemcitabine-cisplatin significantly improved both EFS (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), along with a 10% improvement in pCR rate.

Using the Signatera™ tumor-informed ctDNA assay, the investigators analyzed paired plasma (n=460 at baseline; n=422 pre-cystectomy) and urine samples (n=205 at baseline; n=183 pre-cystectomy) from patients enrolled in NIAGARA. The key finding was that utDNA and ctDNA appear to provide complementary, not redundant, clinical information.

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ASCO Genitourinary Cancer Symposium 2026: Highlights

At baseline, 85% of patients were utDNA positive, which decreased to 55% following neoadjuvant treatment. Importantly, utDNA clearance prior to cystectomy was 11% higher in the durvalumab arm versus the comparator arm (38.5% vs. 27.1%), mirroring the treatment benefit seen with plasma ctDNA clearance. Patients who achieved utDNA clearance had significantly improved EFS compared to those with persistent positivity (HR 0.24, 95% CI 0.09–0.62).

While prior analyses have demonstrated that plasma ctDNA negativity pre-cystectomy was not reliably associated with pCR (only 51% of ctDNA-negative patients achieved pCR4), utDNA negativity was far more predictive. 72% of pre-cystectomy utDNA-negative patients achieved pCR, compared to only 18% of utDNA-positive patients. This suggests that utDNA reflects local bladder tumor burden, while ctDNA likely captures systemic micrometastatic disease.

When both biomarkers were evaluated simultaneously, patients who were dual-negative (ctDNA−/utDNA−) had the highest 24-month EFS at 90%, compared to 75% for ctDNA−/utDNA+ and 55% for ctDNA+/utDNA+ patients. This underscores the value of a combined biomarker strategy for risk stratification and potential future treatment de-escalation or escalation decisions.

These data represent the largest phase III dataset to-date characterizing utDNA in MIBC, and highlights a future in which liquid biopsy from both blood and urine may meaningfully guide perioperative decision-making, including patient selection for bladder-sparing strategies or the need for intensified adjuvant therapy.

SWOG S1602: BCG Strain Equivalence and the Limits of T Cell Priming

Presented by Dr. Rob Svatek of UTSA, the SWOG S1602 trial (NCT03091660)4 addressed two clinically pressing questions in BCG-naïve high-grade NMIBC: whether Tokyo BCG is non-inferior to the widely used TICE BCG strain, and whether intradermal BCG priming prior to intravesical therapy can improve outcomes.

The three-arm randomized phase III trial enrolled 984 patients with carcinoma in situ (CIS), high-grade Ta, or high-grade T1 bladder cancer, randomizing them 1:1:1 to intravesical TICE BCG (50 mg), intravesical Tokyo BCG (80 mg), or intradermal priming with Tokyo BCG followed by intravesical Tokyo BCG. The primary endpoint was high-grade recurrence-free survival (HG-RFS).

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ASCO Genitourinary Cancer Symposium 2026: Highlights

The headline result was that Tokyo BCG demonstrated non-inferiority to TICE BCG, with a hazard ratio of 0.82 (95.8% CI 0.63–1.08) and estimated 5-year HG-RFS rates of 64% versus 58%, respectively5. In the CIS subgroup, biopsy-proven complete response at six months was 66.4% with Tokyo versus 70.2% with TICE, with a difference well within the pre-specified non-inferiority margin of 20%. These findings are especially clinically significant given the ongoing BCG shortage that has challenged urologic oncology practices worldwide. Tokyo BCG represents a viable alternative that can be incorporated into standard practice.

However, the priming strategy did not demonstrate benefit. Intradermal BCG priming yielded an identical hazard ratio of 1.0 compared to Tokyo BCG alone, and complete response rates in CIS patients were essentially equivalent (66.4% without priming vs. 67.0% with priming). Interestingly, PPD conversion (used as a surrogate for systemic immune sensitization) was higher with Tokyo BCG (33%) than TICE (22%), yet PPD conversion did not correlate with improved HG-RFS (HR 0.91), suggesting that skin-test conversion is not a valid surrogate for intravesical efficacy.

From a toxicity standpoint, Tokyo BCG was associated with slightly higher rates of grade 3 adverse events (11% vs. 5% for TICE) and a modest but statistically significant decrease in urinary quality of life as measured by the Bladder Cancer Index at six months, though this difference was below the threshold of clinical meaningfulness.

SWOG S1602 provides definitive level 1 evidence supporting Tokyo BCG as a non-inferior alternative to TICE, offering a practical solution to BCG supply constraints without compromising patient outcomes.

Conclusion

ASCO GU 2026 delivered practice-defining data across the bladder cancer disease spectrum. KEYNOTE-B15 signals a potential paradigm shift in neoadjuvant MIBC treatment, NIAGRA biomarker analysis charts a course towards liquid-biopsy precision perioperative management, and SWOG S1602 resolves a pressing clinical question regarding BCG strain equivalence. Overall, these studies reflect a remarkable pace of progress in bladder cancer therapeutics and diagnostics and point towards a promising future.

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ASCO Genitourinary Cancer Symposium 2026: Highlights

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EAU 2026 Bladder Cancer Highlights



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The 2026 European Association of Urology Congress was held in London, UK from March 13-16, 2026, and once again confirmed bladder cancer as one of the most dynamic areas in uro-oncology. Across plenary sessions, rapid-fire debates, abstracts and posters sessions, a consistent message emerged: treatment is moving beyond uniform algorithms toward more individualized, risk-adapted, and response-adapted pathways. The central question is no longer simply whether to intensify or de-intensify treatment, or whether to preserve the bladder or proceed with radical cystectomy, but how to select the right strategy for the right patient.
A plenary session chaired by Laura Mertens and Morgan Rouprêt focused on treatment tailoring across NMIBC and MIBC, addressing the balance between intensification and de-intensification, as well as bladder preservation versus RC.

The first state-of-the-art lecture addressed BCG-naïve high-risk NMIBC. Evanguelos Xylinas discussed the phase III CREST, ALBAN, and POTOMAC trials, which collectively support the potential role of a combination of systemic immunotherapy with BCG in selected patients. These studies showed improvements in EFS, but also highlighted the cost of treatment intensification, particularly immune-related toxicity and increased treatment burden. The message was therefore nuanced: combination strategies may become relevant for selected patients, such as those with very high-risk disease, but BCG alone remains an appropriate and effective standard for many BCG-naïve high-risk patients.

The second lecture focused on treatment de-intensification in NMIBC. Roberto Contieri highlighted that active surveillance, office fulguration or laser ablation, and chemoablation for recurrent low grade Ta tumours are no longer merely investigational concepts but are already part of real-world practice in selected patients. These approaches aim to reduce morbidity, anesthesia exposure, patient burden, and healthcare resource use associated with repeated TURBT, while preserving excellent long-term cancer outcomes.

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EAU 2026 Bladder Cancer Highlights

For MIBC, Jeremy Teoh reviewed real-world evidence supporting bladder-sparing strategies. Bladder preservation was presented not as a single intervention, but as a pathway requiring optimization at every step: accurate staging, multiparametric assessment, maximal TURBT, careful patient selection, integration of systemic therapy and radiotherapy, and structured surveillance. In selected patients, TMT may achieve oncological outcomes comparable to RC, but these results depend on high-quality initial resection, reliable staging, multidisciplinary expertise, and a clear salvage strategy.

The final state-of-the-art lecture addressed whether all patients still require surgery after neoadjuvant therapy. Alexandre Zlotta emphasized that although immunotherapy and novel perioperative combinations have increased pCR rates, current tools remain insufficient to safely identify patients who can omit cystectomy outside clinical trials. Trials such as NIAGARA and KEYNOTE-905/EV-303 have shown important gains with intensified perioperative strategies, including improvements in pCR and survival endpoints, but toxicity remains clinically relevant. Biomarkers, particularly ctDNA and urinary tumor DNA, may refine post-neoadjuvant decision-making and help identify candidates for bladder preservation, although prospective validation remains essential.

Several important studies were also presented in the late-breaking and high-impact abstracts session. Among NMIBC studies, Peter J. Boström presented FinnBladder-9, a randomized trial evaluating blue-light TURBT and optimized adjuvant MMC in patients with LG disease at high risk of recurrence. In this 9-centre study including 510 patients, the combination of fluorescence-guided resection and six weekly optimized MMC instillations significantly reduced recurrence compared with standard WLC TURBT without adjuvant therapy, with an HR of approximately 0.42. No meaningful differences were observed across the other treatment arms, and the progression rate remained very low at 1.6%. These data reinforce the additive value of improving both resection quality and intravesical therapy delivery.

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EAU 2026 Bladder Cancer Highlights

Targeted intravesical therapy was explored by Antoni Vilaseca, who reported first-in-human phase I results of erdafitinib delivered through TAR-210, an intravesical drug-releasing system, in FGFR-altered NMIBC. In BCG-experienced HR NMIBC, 12-month RFS reached 83%. In the IR chemoablation cohort, CR was observed in 89% of patients at the first or second disease evaluation, with 81% achieving CR already at 3 months. Treatment was generally well tolerated, with grade ≥3 toxicity reported in 5% and minimal systemic exposure. These findings support the rationale for sustained local FGFR inhibition and suggest a potential future role for biomarker-driven intravesical therapy.

In MIBC, Neal Shore presented surgical outcomes from KEYNOTE-905/EV-303, evaluating perioperative enfortumab vedotin plus pembrolizumab in cisplatin-ineligible patients. The combination significantly improved pCR, 57.1% versus 8.6%, EFS, HR 0.40, and OS, HR 0.50, compared with surgery alone. Importantly, treatment intensification did not compromise surgical feasibility, with comparable RC rates and no apparent increase in perioperative complications. These data suggest that highly active systemic combinations can be integrated into standard surgical pathways without negatively affecting perioperative delivery.

Peng Zhang reported the final results of the phase Ib/II HOPE-03 study evaluating disitamab vedotin plus tislelizumab in HER2-positive, locally advanced MIBC. In this single-arm trial of 59 patients, the combination achieved an ORR of 91.5%, with a complete clinical response in 64.4%. Most patients proceeded to radiotherapy-based bladder-sparing treatment, and 95.5% achieved clinical complete response at re-TURBT. At a median follow-up of 24.3 months, 12- and 18-month EFS rates were 92.8% and 89.4%, respectively, with a bladder preservation rate of 100% among patients remaining on study. Toxicity was manageable, with grade 3 to 4 adverse events in 12.1% and no treatment-related deaths.

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EAU 2026 Bladder Cancer Highlights

Further insights came from the cutting-edge strategies session, where James Catto presented the final survival analysis of BladderPath, comparing an MRI-guided pathway with standard TURBT-based staging in newly diagnosed bladder cancer. In this randomized study of 143 patients, upfront multiparametric MRI reduced time to definitive treatment from 98 to 53 days. No difference in OS was observed, HR 0.67, but MRI-guided management was associated with improved bladder cancer-specific survival, HR 0.36, driven by earlier treatment of MIBC. Importantly, no signal of harm emerged despite reduced reliance on immediate TURBT.

Overall, EAU 2026 highlighted a clear evolution in bladder cancer care. Across NMIBC and MIBC, the field is moving toward more precise treatment allocation, better local treatment quality, biomarker-informed decisions, and carefully selected bladder preservation. The next step will be to standardize selection criteria, validate response assessment tools, and ensure that innovation translates into durable, patient-centered benefit.

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At the Bladder Cancer Advocacy Network (BCAN), we are dedicated to turning today's research into tomorrow's breakthroughs for patients and their loved ones. Our mission is to accelerate the most promising discoveries in bladder cancer research, funding both emerging and established investigators who are pushing boundaries to develop lifesaving treatments and improve patient care.

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Discover more about BCAN's commitment to advancing research and how our grants are fueling innovation at **bcan.org/research**.



Join us for our **Walks to End Bladder Cancer** in the Spring of 2026. Our in-person and virtual walks raise spirits and raise funds to defeat bladder cancer. Please visit **bcanwalk.org**.

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Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates



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The "Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates" session, held on Friday, March 13, during the EAU Congress in London, once again stood out as one of the most popular and well-attended sessions of the meeting. Now in its ninth edition, the session adopted a renewed format, designed to make the discussion even more dynamic, focused, and provocative. Coordinated by Dr. Ashish Kamat and Dr. Arnulf Stenzl, the session brought together leading experts to address some of the most frequent and clinically relevant controversies in bladder cancer management.

The format was built around five real-world clinical cases, each used as a springboard for concise, opposing viewpoints and interactive discussion. This structure created a lively exchange between speakers and audience, highlighting the persistent areas of uncertainty that clinicians face in daily practice. The session ultimately underscored how bladder cancer management continues to evolve, with many decisions still requiring careful balance between guideline recommendations, emerging evidence, patient factors, and clinical judgement.

Urinary markers vs. cystoscopy: Is it time to ditch the scope?

The first case, introduced by Dr. Paolo Gontero, focused on whether urinary biomarkers can replace cystoscopy in NMIBC surveillance. An 82-year-old former smoker with cardiac comorbidities underwent en bloc TURBT and single postoperative MMC for a solitary 3.5-cm tumor. Final pathology showed G2 low-grade Ta disease.

After negative cystoscopies at 3, 9, and 15 months, cystoscopy was omitted at 21 months because a multiplex urinary biomarker was negative. At 26 months, the marker became positive, while cytology, upper tract imaging, and cystoscopy were negative. At 37 months, the marker was again positive, and cystoscopy detected two 5-mm papillary lesions, confirmed as low-grade Ta recurrence.

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Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates

Dr. Jeremy Teoh argued in favour of biomarker-guided surveillance, emphasizing the patient's very low progression risk, the high quality of the initial en bloc resection, and the growing performance of contemporary urinary markers, particularly for high-grade disease. He cited emerging randomized evidence, including DaBlaCa-15 and UroFollow, suggesting that marker-based surveillance can reduce cystoscopy burden without compromising detection of clinically meaningful disease in selected patients.

Dr. Laura Mertens defended cystoscopy as the current standard. She stressed that urinary markers have limited sensitivity for low-grade recurrences, which remain the most common events in low-grade NMIBC. She also highlighted the risk of false positives: in low-prevalence surveillance settings, repeated biomarker testing may trigger unnecessary cystoscopy, imaging, cytology, or biopsies.

The debate, enriched by the contribution of Dr. Carmen Mir, did not support a simple "cystoscopy versus biomarker" dichotomy. Rather, it highlighted the need for risk-adapted surveillance, in which biomarkers may help reduce unnecessary procedures in carefully selected patients, but should not yet replace cystoscopy altogether.

High-risk BCG-naïve NMIBC: BCG plus IO, new standard or overreach?

The second debate, introduced by Dr. Ashish Kamat, addressed treatment intensification in BCG-naïve high-risk NMIBC. The case involved a 49-year-old fit patient with HG Ta disease and concomitant CIS after complete TURBT, with muscle present and uninvolved. The key question was whether initial therapy should remain BCG alone or move toward BCG combined with systemic checkpoint inhibition.

Dr. Neal Shore supported the combination strategy. He argued that recent phase III data has changed the discussion, particularly CREST and POTOMAC, where adding sasanlimab or durvalumab to BCG improved recurrence-related endpoints compared with BCG alone. His position was that, in high-risk NMIBC, recurrence should not be dismissed as a minor event, since it may lead to repeated TURBTs, salvage therapies, BCG-unresponsive disease, and eventual cystectomy. Although systemic IO increases toxicity, he considered this acceptable for carefully selected patients with the highest-risk disease, especially when bladder preservation is a major priority.

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Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates

Dr. Ekaterina Laukhtina took the opposite view. She cautioned that the current benefit is largely confined to recurrence-based endpoints, while mature evidence for improved progression, cystectomy-free survival, metastasis-free survival, or OS is still lacking. She also emphasized the substantial increase in grade ≥3 and immune-related adverse events, together with greater treatment complexity, uncertain cost-effectiveness, and the risk of overtreating a heterogeneous high-risk population.

The final comment by Dr. Arnulf Stenzl emphasized that BCG plus IO should be viewed as a promising but not universal strategy. For now, it appears most appropriate for selected very-high-risk patients, within careful shared decision-making, while BCG alone remains a valid standard for many BCG-naïve high-risk cases.

TMT for MIBC: Radiation, Responsibility, and Recurrences - Who Manages the Fallout, and How?

The third debate focused on the long-term consequences of bladder-preserving TMT for MIBC and the shared responsibility for managing treatment-related toxicity. Dr. Paramananthan Mariappan introduced the case of a 79-year-old fit patient with HG T2 urothelial carcinoma, no CIS, no hydronephrosis, and no metastatic disease after complete TURBT. The patient elected for bladder preservation and received chemoradiation with 5-FU, MMC, and 55 Gy in 20 fractions.
Despite achieving local tumor control, his post-treatment course was complex. During radiotherapy he developed pulmonary embolism requiring anticoagulation. Three months after treatment, cystoscopy showed no recurrence, but a markedly reduced bladder capacity. Imaging revealed a thick-walled bladder with bilateral hydroureteronephrosis and AKI. Renal function did not improve with catheter drainage, requiring bilateral nephrostomies. Over time, he developed recurrent infections, nephrostomy dislodgements, urge incontinence, intermittent hematuria, and eventually stopped surveillance cystoscopy because of pain related to a contracted bladder.

Dr. Antoine van der Heijden emphasized the urologist's central role in recognizing and treating late GU toxicity after pelvic radiotherapy. Radiation injury may present months or years after treatment and includes radiation cystitis, hematuria, strictures, fistulae, bladder fibrosis, reduced capacity, upper tract obstruction, and secondary malignancies. Management often requires cystoscopy, clot evacuation or fulguration, bladder irrigation, endoscopic procedures, ureteral drainage, or urinary diversion.

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Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates

Dr. Neha Vapiwala argued that radiation oncologists must also take ownership. She stressed the importance of better patient selection, prediction of radiosensitivity, toxicity biomarkers, patient-reported outcomes, and structured survivorship pathways. Prehabilitation, rehabilitation, close follow-up, and dedicated pelvic radiotherapy toxicity clinics were proposed as practical ways to reduce morbidity.

The discussion, enriched by the contribution of Dr. Alison Birtle, moved beyond specialty boundaries. TMT can preserve the bladder, but toxicity may be clinically significant. Optimal care requires urologists and radiation oncologists to share responsibility before, during, and long after treatment.

Bladder preservation after cCR in MIBC: data-driven strategy or risky business?

The fourth debate, introduced by Dr. Benjamin Pradere, addressed whether RC can be avoided in selected patients with MIBC who achieve a cCR after NAC. The case involved an 80-year-old fit patient with cT2 urothelial carcinoma, minor micropapillary component, CIS, and LVI. After six cycles of ddMVAC, restaging with FDG-PET, MRI, cystoscopy with biopsy, and urine cytology showed no evidence of residual disease.

Dr. Fernando Maluf supported bladder preservation as a rational, increasingly data-driven strategy. He argued that modern systemic therapies are producing higher pCR rates, particularly with chemoimmunotherapy and EV plus pembrolizumab combinations. In his view, the goal is not to omit cystectomy based on clinical impression alone, but to build a precision framework combining pathology, MRI, cystoscopy, ctDNA, utDNA, and molecular profiling. He highlighted response-adapted studies showing that patients with carefully defined cCR may experience favorable metastasis-free and overall survival, suggesting that some patients could safely avoid immediate RC.

Dr. Bogdana Schmidt argued for caution. She acknowledged the appeal of avoiding cystectomy, but stressed that cCR remains an imperfect surrogate for true pCR. Even in highly selected cohorts, bladder recurrences, invasive relapses, and delayed salvage cystectomies remain clinically relevant. She also emphasized that ctDNA may help predict systemic relapse, but is less reliable for detecting local bladder recurrence, meaning that negative molecular testing cannot replace intensive bladder surveillance.

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Common Problems and Controversies in Bladder Cancer: Rapid-fire Debates

In his concluding remarks, Dr. Arnulf Stenzl highlighted both the promise and the fragility of response-adapted bladder preservation after neoadjuvant therapy. This strategy is moving rapidly forward, but outside clinical trials remains appropriate only for exceptionally selected patients, with rigorous restaging, molecular assessment, and a clear salvage plan. Emerging tools such as AI and ctDNA may further support the implementation of this approach.

MIBC systemic therapy: intensify early or adapt after surgery?

The final debate, introduced by Dr. Matthew Galsky, addressed perioperative systemic therapy for MIBC. The case involved a 58-year-old woman with HG MIBC, focal microcystic differentiation, suspected cT3 disease on MRI, preserved renal function, and positive baseline ctDNA. The central question was whether treatment should be intensified upfront with perioperative IO-based therapy or tailored after RC according to pathologic and molecular risk.

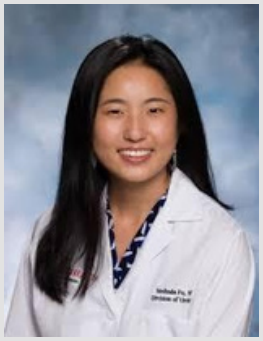
Dr. Thomas Powles supported early intensification. He argued that the treatment landscape has changed substantially, with recent perioperative trials showing not only higher pCR rates, but also improvements in EFS and OS. He emphasized NIAGARA, where adding durvalumab to cisplatin-based NAC followed by adjuvant durvalumab improved pCR, EFS, and OS without compromising cystectomy delivery. He also highlighted EV plus pembrolizumab data, showing major gains in pCR and survival compared with cisplatin-based chemotherapy. For Dr. Powles, these results suggest that the therapeutic window before surgery should not be missed, particularly in patients with high-risk features and molecular evidence of disease.

Dr. Patrizia Giannatempo argued for a more selective post-operative strategy. Her central point was that not all patients require adjuvant IO, especially those achieving pCR or remaining ctDNA-negative after RC. She emphasized that ctDNA dynamics may refine risk beyond pathology alone and help identify patients who truly need post-operative escalation. The IMvigor011 design was presented as an example of this approach, with serial ctDNA monitoring used to select patients for adjuvant atezolizumab only after molecular relapse.

The debate, which also featured Dr. Felix Guerrero Ramos, contrasted two increasingly credible strategies: treating early to maximize the probability of cure versus using molecular residual disease to avoid overtreatment. The likely future may combine both principles, with perioperative intensification for biologically high-risk patients and ctDNA-guided adaptation after surgery.

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Bladder Preservation in Muscle Invasive Bladder Cancer Current Trials and Future Directions



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For over two decades, standard therapy for eligible patients with muscle-invasive bladder cancer (MIBC) has been platinum-based neoadjuvant chemotherapy (NAC) followed by radical cystectomy (RC). While RC remains central for local control, it carries morbidity, with complication rates still approaching 60% within 90 days. These tradeoffs have accelerated interest in bladder-preservation strategies. Historically, trimodal therapy (TMT) has been the principal alternative for select patients. More recently, emerging data on immune checkpoint inhibitors (ICIs) and antibody-drug conjugates (ADCs) have raised the possibility of novel systemic-based organ-preservation regimens. Any strategy that omits cystectomy, however, must prove oncologic safety. Pathologic complete response (pCR) may serve as a useful benchmark given its association with reduced recurrence and improved overall survival after NAC, but pCR is an imperfect surrogate and OS remains the definitive endpoint against which preservation strategies must ultimately be judged.

The National Comprehensive Cancer Network and the International Bladder Cancer Group consider bladder preservation beyond TMT investigational and recommend it only within clinical trials that include rigorous surveillance. Several phase 2 trials testing modern systemic regimens, with or without radiotherapy, are now underway and beginning to define the contours of this approach.

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Bladder Preservation in Muscle Invasive Bladder Cancer Current Trials and Future Directions



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RETAIN 2 evaluates dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) plus nivolumab and uses DNA damage response (DDR) alterations (e.g., ATM, ERCC2, RB1) to guide bladder preservation. Patients with clinical complete response (cCR) on TURBT, cytology, and cross-sectional imaging, and harboring at least one DDR mutation, enter a surveillance arm rather than proceeding to immediate cystectomy. Alliance A031701 similarly uses DDR alterations for selection but pairs gemcitabine and cisplatin with genomically guided bladder preservation. Key endpoints include bladder-intact survival, overall survival (OS), and pT0 rates in DDR-altered tumors undergoing RC. SASN-SPARING builds on the neoadjuvant treatment by adding subcutaneous sasanlimab, evaluating the feasibility of a maintenance-immunotherapy strategy after response to initial systemic therapy. The BRIGHT trial combines hypofractionated photon radiotherapy (20 fractions over four weeks) after an initial response to neoadjuvant therapy with one year of pembrolizumab. Its primary endpoint is 3-year event-free survival (EFS); secondary endpoints include muscle-invasive recurrence–free survival, metastasis-free survival (MFS), OS, and salvage cystectomy rate.

Early results from these and related studies have been encouraging. RETAIN 2 reported a preliminary 2-year MFS of 68% and a 71% cCR rate among DDR-mutant tumors. HCRN GU 20-444 reported a 43% cCR rate in cisplatin-ineligible or cisplatin-declining patients treated with maximal TURBT, two cycles of pembrolizumab, and maintenance pembrolizumab for responders with no metastases at a median follow up of 11 months. SURE-02 (pembrolizumab plus sacituzumab govitecan followed by 13 cycles of adjuvant pembrolizumab) reported a 38.8% cCR rate (n=49), including 43% among patients with variant histology and 62% among those with luminal subtype tumors, with no metastases at 14 months and no grade 4–5 toxicities and grade 3 events in only 16% of patients.

Important caveats temper this enthusiasm. The phase 3 studies that have demonstrated the clearest survival benefit in MIBC (e.g., NIAGARA, EV-303, EV-304) retain RC as a backbone, underscoring its curative role for many patients. Retrospective data continue to show substantial local recurrence without cystectomy even after apparent cCR, reflecting the limits of current clinical restaging. Trials, therefore, aim to reduce undertreatment by strengthening local control (e.g., consolidative radiotherapy) and/or extending systemic exposure with a maintenance phase after cCR. It is also worth noting that bladder-intact survival does not necessarily translate to superior quality of life. In non–muscle-invasive bladder cancer, the CISTO trial found that RC did not worsen 12-month physical function and improved several patient-reported domains relative to organ-preserving approaches, a reminder that "preservation" and "patient benefit" are not synonymous.

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Bladder Preservation in Muscle Invasive Bladder Cancer Current Trials and Future Directions

Patient selection is therefore central to the success of any organ-preservation strategy. Circulating tumor DNA (ctDNA), tumor-derived cell-free DNA detectable in blood, has emerged as a promising biomarker. Baseline ctDNA positivity before cystectomy predicts adverse pathology, including nodal involvement and extravesical extension, and on-treatment ctDNA dynamics correlate with response and recurrence risk. A limitation is that ctDNA may miss purely intravesical relapse, where tumor shedding into circulation is minimal. Urinary tumor DNA (utDNA) can complement ctDNA in this setting, and combined liquid biopsy approaches, as deployed in correlative analyses from NIAGARA, are informing ongoing biomarker-driven trials.

Cisplatin-based NAC followed by RC has been a standard for cisplatin-eligible patients with MIBC, while perioperative immunotherapy and emerging perioperative enfortumab vedotin and pembrolizumab strategies continue to push pCR rates higher across eligibility groups. As pCR rates rise with ICIs and ADCs, bladder preservation becomes increasingly attractive for the subset of patients who may achieve durable disease control with systemic therapy (with or without radiotherapy) and close surveillance. The principal challenge is identifying that subset. Traditional clinical staging with TURBT, cytology, and cross-sectional imaging can understage residual disease, and patients risk missing the curative window if RC is deferred inappropriately. Biomarkers such as ctDNA, potentially paired with utDNA, somatic mutations and gene expression-based subtypes may better predict pCR and response durability than clinical assessment alone, and incorporating these tools prospectively into selection algorithms will be essential.

Until prospective trials validate selection criteria, surveillance protocols, and maintenance regimens after cCR, bladder preservation beyond TMT should remain trial-based as recommended by the IBCG. Ongoing studies will ultimately define which patients can safely forgo local control without compromising cure, and which require RC as a curative anchor. The next several years should yield pivotal data, but in the interim, careful patient selection, multidisciplinary discussion, and enrollment on clinical trials remain the standard of care for patients considering an organ-preservation approach.

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