# Bladder Cancer Research Review™

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Issue 17 - 2025


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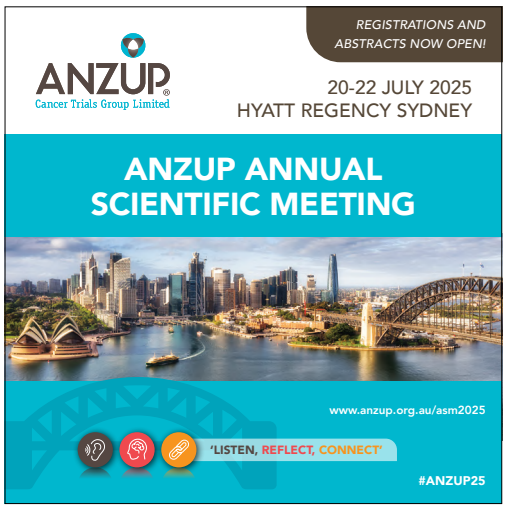
### Abbreviations used in this issue:

**AE** = adverse event; **ASA** = American Society of Anesthesiologists; **ddMVAC** = dose-dense methotrexate-vinblastine-doxorubicin-cisplatin; **HR** = hazard ratio; **MIBC** = muscle-invasive bladder cancer; **mpMRI** = multiparametric MRI; **OR** = odds ratio; **OS** = overall survival; **PARP** = poly (ADP-ribose) polymerase; **pCR** = pathological complete response; **PD-L1** = programmed death ligand-1; **QoL** = quality of life; **RFS** = recurrence-free survival; **TURBT** = transurethral resection of bladder tumour.



## Welcome to the latest issue of Bladder Cancer Research Review

We begin with the phase 2 AURA trial which demonstrated the promising efficacy and safety of avelumab plus cisplatin-based neoadjuvant chemotherapy (especially ddMVAC) in patients with MIBC. This is followed by the UK-based BladderPath trial which found that staging with flexible cystoscopic biopsy plus mpMRI safely shortened the time to definitive treatment by 45 days in patients with MIBC, in comparison to initial TURBT. Another interesting article on the IMMERSE trial reported that patients who underwent immediate second resection at the time of initial TURBT had significantly improved detrusor sampling rates in comparison to standard TURBT, with significantly reduced residual disease at restaging. We conclude with an interesting study from the Netherlands which described the long-term QoL trajectories in patients with bladder cancer for up to 8 years after radical cystectomy, with the authors highlighting the need for pre- and post-surgical supportive care interventions.

I hope you find this review interesting and informative, and I look forward to reading your feedback.

Warm regards,


**Dr Brendan Dias**
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## Avelumab-based neoadjuvant therapy in patients with muscle-invasive bladder cancer (AURA Oncodistinct-004)

**Authors:** Blanc J et al.


**Summary:** The open-label phase 2 AURA trial evaluated the efficacy of safety of neoadjuvant avelumab in combination with other regimens in cisplatin-eligible and -ineligible patients with muscle-invasive bladder cancer (MIBC). The trial enrolled 137 evaluable patients across France and Belgium with non-metastatic MIBC undergoing radical cystectomy. Cisplatin-eligible patients (n=79) were randomly assigned to avelumab with dose-dense methotrexate-vinblastine-doxorubicin-cisplatin (ddMVAC; n=39) or avelumab with gemcitabine-cisplatin (n=40). Cisplatin-ineligible patients (n=58) were randomly assigned to receive avelumab monotherapy (n=29) or avelumab with paclitaxel-gemcitabine (n=29). At a follow-up of 36 months, the pCR rates (primary outcome) in the cisplatin-eligible cohort were 58% (95% CI 42–72) in the avelumab plus ddMVAC arm and 53% (95% CI 37–68) in the avelumab plus gemcitabine-cisplatin arm; the respective OS rates were 87% (95% CI 76–98) and 67% (95% CI 53–84). The pCR rates in the cisplatin-ineligible cohort were 14% (95% CI 6–31) in the avelumab plus paclitaxel-gemcitabine arm and 32% (95% CI 18–51) in the avelumab arm; the respective OS rates were 48% (95% CI 33–71) and 42% (95% CI 27–65). The authors noted that there were no significant safety concerns.


**Comment:** This was a phase 2 trial evaluating the efficacy and safety of neoadjuvant immunotherapy-based regimens in patients with MIBC. The trial randomised cisplatin-eligible patients to receive avelumab with either ddMVAC or gemcitabine-cisplatin. Cisplatin-ineligible patients received avelumab alone or combined with paclitaxel-gemcitabine. The trial demonstrated that avelumab combined with standard cisplatin-based neoadjuvant chemotherapy – especially ddMVAC – had high complete response rates and strong long-term survival rates in cisplatin-eligible MIBC patients. In contrast, for cisplatin-ineligible patients, avelumab monotherapy appeared to be clinically effective, with no additional benefit observed from the addition of paclitaxel-gemcitabine. These results support the use of the ddMVAC regimen as a potential chemotherapy partner for neoadjuvant chemo-immunotherapy combinations in future phase 3 trials, particularly focusing on ddMVAC plus avelumab versus the current standard such as the durvalumab plus gemcitabine-cisplatin regimen, which showed benefit in the NIAGARA trial that was published last year.


***Reference: J Immunother Cancer. 2025;13(5):e012045***
Abstract


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## Randomized comparison of magnetic resonance imaging versus transurethral resection for staging new bladder cancers: results from the prospective BladderPath trial

**Authors:** Bryan RT et al., on behalf of the BladderPath Collaborative Group

**Summary:** The BladderPath investigators explored whether flexible cystoscopic biopsy and multiparametric MRI (mpMRI; with subsequent TURBT if indicated) could feasibly shorten the time to correct treatment versus initial TURBT in patients with MIBC. Eligible patients (n=143) across 17 hospitals in the UK with suspected new bladder cancer were randomised to TURBT-staged care (n=72; 15 MIBCs; 55 men) or mpMRI-staged care (n=71; 14 MIBCs; 53 men). Overall, 92% of patients with suspected MIBC underwent mpMRI, after which 22% received the correct treatment without needing TURBT (feasibility outcome). Patients with MIBC who underwent initial mpMRI had a significantly shorter median time to correct treatment versus TURBT (53 [95% CI 20–89] vs. 98 days [95% CI 72–125]; p=0.02). There was no significant difference in time to correct treatment with mpMRI versus TURBT for patients with non-MIBC (17 [95% CI 8–25] versus 14 days [95% CI 10–29]; p=0.67). No serious AEs were observed.

**Comment:** The BladderPath trial is a UK-based randomised trial that evaluated whether staging with flexible cystoscopic biopsy plus mpMRI could safely and efficiently shorten the time to definitive treatment compared to TURBT in patients with bladder cancer. The trial demonstrated the feasibility of using mpMRI in a UK setting. The mpMRI-based clinical pathway was both feasible and efficient when compared to the standard TURBT-based pathway to expedite treatment planning, thereby strengthening the case for adapting clinical guidelines to include mpMRI-based staging for bladder cancer, especially in patients with suspected muscle-invasive disease.

***Reference: J Clin Oncol. 2025;43(12):1417–28***
Abstract

## Treatment efficacy and molecular dynamics of neoadjuvant durvalumab and olaparib in resectable urothelial bladder cancer: The NEODURVARIB trial

**Authors:** Rodríguez-Moreno JF et al.

**Summary:** The objective of the phase 2 NEODUVARIB trial was to examine the effects of neoadjuvant durvalumab (anti-PDL1 inhibitor) plus olaparib (PARP inhibitor) on the molecular profiles of patients with resectable urothelial bladder cancer. Researchers compared gene expression patterns and mutational profiles before and after treatment in 29 patients with T2–T4a bladder cancer. Overall, 13 patients achieved a pCR (44.8%) and 26 patients underwent cystectomy (90%). Throughout treatment, there were no changes in tumour mutational burden, homologous recombination deficiency or mutational pattens. Responders showed increases in circulating $CD4^+$ $CD27^-$ $CD28^-$ T cells, whereas non-responders showed transcriptomic alterations.

**Comment:** NEODURVARIB is a phase 2 clinical trial that assessed the molecular modifications induced by the combination of durvalumab plus olaparib as neoadjuvant treatment in bladder cancer. A pathologic response rate of 44.8% was achieved in the trial, which is comparable to cisplatin-based regimens in bladder cancer. While the total numbers of recruited patients were low (29 patients), the trial did demonstrate promising efficacy with a non-chemotherapy regimen consisting of an anti-PDL1 inhibitor and a PARP inhibitor. The trial paves the way for phase 3 randomised clinical trials comparing standard of care neoadjuvant chemotherapy with immunotherapy and PARP inhibitor combination therapies.

***Reference: Clin Cancer Res. 2025;31(9):1644–56***
Abstract

## Tumor location at trans-urethral resection is predictive of ipsilateral pelvic lymph-nodal metastases in patients undergoing radical cystectomy for bladder cancer

**Authors:** Cianflone F et al.

**Summary:** These Italian researchers retrospectively evaluated whether tumour location at the time of diagnostic TURBT was predictive of ipsilateral pelvic lymph-nodal metastasis in 239 patients who underwent radical cystectomy for bladder cancer between 2014–23. In comparison to the rest of the bladder, there was a higher percentage of ipsilateral positive lymph-nodes with right-sided tumours (p=0.047) and left-sided tumours (p=0.02). Linear regression analyses revealed that in all of the ipsilateral lymph-nodes removed, significantly higher percentages of ipsilateral positive lymph-nodes were seen with right-sided tumours (p=0.019) and left-sided tumours (p=0.003).

**Comment:** This trial looked at 239 patients who underwent radical cystectomy from a single institution in Italy, and retrospectively analysed risk factors for ipsilateral lymph-nodal metastasis. They found that lateral tumour location (left or right) was associated with a higher percentage of positive lymph-nodal metastasis. While the retrospective nature of the study is a limitation, the study does highlight the need for better predictors for lymph-nodal metastasis in bladder cancer, and perhaps paves the way for future nomograms to consider incorporating tumour location as a predictor for lymph-nodal metastasis.

***Reference: Urol Oncol. 2025;43(5):331.e1–7***
Abstract

Bladder Cancer Research Review™

### Independent commentary by Dr Brendan Dias

Dr Brendan Dias is a Consultant Urologist and Renal surgeon at Western Health, Melbourne. He is also a visiting medical officer at Epworth Healthcare, Healthscope, Ramsay healthcare and St Vincents Private Hospitals Melbourne. Dr Dias holds a professional academic appointment at the University of Melbourne as a senior clinical lecturer. He is also an examiner with the Royal Australasian College of Surgeons (RACS) and the University of Melbourne (UoM). Dr Dias has a subspecialty interest in uro-oncology, minimally invasive surgery, vascular access surgery, male and female reconstructive and functional urology. He has authored over 50 peer reviewed publications and co-authored a book chapter on the surgical approach to robot assisted prostatectomy in kidney transplant recipients. He has been providing urological services to Melbourne's Western and North-western metropolitan region through his public appointment at Western Health. He has a specific interest in the management of bladder and prostate cancer as well as the surgical management of benign prostatic hyperplasia. He has pioneered the development and implementation of day case surgery for benign prostatic enlargement (Day Case HoLEP) at Western Health and is committed to the delivery of evidence based urological and renal services to his patients.

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‡Long-term exploratory, *post hoc* analysis of the overall population; median follow-up 38.0 months and 39.6 months for BAVENCIO + BSC vs BSC alone, respectively.1,2 mOS from the start of 1L maintenance in the initial analysis was 21.4 months vs 14.3 months with BSC alone; HR: 0.69 (95% CI 0.56, 0.86); 2-sided *P*=0.001; median follow-up >19 months.†3,4

†In patients whose disease has not progressed with 1L platinum-based induction CT.1–6

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In the JB100 trial, the most common adverse reactions (≥20%) were fatigue, musculoskeletal pain, urinary tract infection and rash. The most common Grade ≥ 3 adverse reaction was urinary tract infection.4

**1L**, first-line; **BSC**, best supportive care; **CT**, chemotherapy; **EQ-5D-5L**, EuroQol five-level EQ-5D; **FBISI-18**, National Comprehensive Cancer Network/Functional Assessment of Cancer Therapy Bladder Symptom Index-18; **JB100**, JAVELIN Bladder 100; **mOS**, median overall survival; **PRO**, patient-reported outcome; **QoL**, quality of life

**1.** Grivas P, *et al. ESMO Open.* 2023;8(6):102050. **2.** Sridhar SS, *et al.* Abstract No. 508. Presented at the 2023 ASCO Genitourinary Cancers Symposium, February 16–18, 2023; San Francisco, CA, USA. **3.** Powles T, *et al. NEJM.* 2020;383(13):1218–1230. **4.** BAVENCIO® Approved Product Information. **5.** Grivas P, *et al. Eur Urol.* 2023;83(4):320–328. **6.** Powles T, *et al.* Abstract 4515. Presented at the 2023 ASCO Annual Meeting, June 2–6, 2023; Chicago, IL, USA.

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## Immediate second resection versus restage transurethral resection of bladder tumor: A prospective randomized clinical trial (IMMERSE trial)

**Authors:** Kumar S et al.

**Summary:** In the prospective phase 2 IMMERSE trial, 83 patients with non-MIBC undergoing TURBT with complete primary tumour resection were randomly assigned to complete tumour resection with a deep biopsy (standard TURBT; n=44) or complete tumour resection, deep biopsy and additional deep biopsies (immediate second resection; n=39). A significantly higher proportion of immediate second resection cases had detrusor muscle versus standard TURBT cases (97% vs. 66%, respectively; p=0.000), and second resection cases had a lower rate of residual disease at restage TURBT (15% vs. 41%; p=0.028). Perioperative complications were comparable between arms.

**Comment:** This randomised trial looked at the role of repeat transurethral resection for the management of non-MIBC. The trial demonstrated that combining a standard TURBT (complete tumour resection with deep biopsies) with additional deep biopsies (immediate second resection) increased the rate of depressor muscle sampling and decreased the incidence of residual tumours at the time of a second resection. However, despite high rates of detrusor muscle sampling, 15% of patients still had residual disease on restaging TURBTs, thereby demonstrating the role for improving the quality of resection during primary TURBT. While the results of the trial continue to advocate for the second resection, there are studies trying to identify parameters where a second resection can be safely avoided, thereby allowing for a more personalised approach to even this current one-size-fits-all strategy.

***Reference: Urol Oncol. 2025;43(5):331.e9–16***
Abstract

## Quantification of micropapillary component on transurethral resection is associated with likelihood of occult lymph node metastasis at radical cystectomy

**Authors:** Wood AM et al.

**Summary:** This US-based study explored whether the proportion of micropapillary component within TURBT samples was associated with lymph-node metastasis at radical cystectomy in patients with micropapillary urothelial cancer. Among a total of 67 patients, 34 underwent radical cystectomy for cT1 disease and 33 had ≥cT2 disease (19/33 were administered neoadjuvant chemotherapy). In cT1 and cT2 patients, the mean percentages of micropapillary components were 35% and 28%, respectively (p=0.25). Univariate analysis revealed that nodal metastasis at radical cystectomy was predicted by clinical stage ≥T2 (OR 2.88; p=0.04) and micropapillary component ≥30% (OR 3.38; p=0.02). Multivariable analysis revealed that pathologic node-positive disease was also predicted by clinical stage ≥T2 (OR 3.73; p=0.018) and micropapillary component ≥30% (OR 4.01; p=0.013). Patients with cT1 disease and micropapillary component <30% had the lowest rate of lymph-node metastasis (18.7%), whereas the highest rate of lymph-node metastasis (75%) was observed in those with ≥cT2 disease and micropapillary component ≥30%.

**Comment:** This is another study looking at predicting lymph-node metastasis in bladder cancer. The study demonstrates that variant histology, specifically micropapillary component in urothelial carcinomas, predicts occult lymph-node metastasis at radical cystectomy. The study highlights the importance of micropapillary component as a poor prognostic indicator in bladder cancer. The conclusions are important when selecting patients with variant histology, and specifically micropapillary component for neoadjuvant chemotherapy. The percentage of micropapillary component could also be a consideration for an early cystectomy in patients with high-grade T1 bladder cancer.

***Reference: Urol Oncol. 2025;43(4):266.e1–7***
Abstract

## Long-term oncologic outcomes and complications of robot-assisted radical cystectomy for the treatment of urothelial carcinoma of the bladder

**Authors:** Lama DJ et al.

**Summary:** To describe the long-term outcomes of robot-assisted radical cystectomy in MIBC and high-risk non-MIBC, these researchers reviewed a prospective database of 510 patients (67% ≥cT2) who underwent robot-assisted radical cystectomy between 2004–20. Overall, 51% of patients underwent continent diversion and 67% of patients with ≥cT2 disease were administered cisplatin-based neoadjuvant chemotherapy. During a median follow-up of 57.1 months, 31% of patients showed recurrence and 23% of patients died as a result of bladder cancer. Complications occurred in 52% of patients, and 41% of these were major grade ≥3 events. After 90 days, the most frequent complications were genitourinary (22%) and infectious (25%) in nature. Multivariable analysis revealed that patients with lymph-node positivity had elevated risks of recurrence (HR 4.58; p<0.001) and death (HR 2.42; p<0.001), and these risks were also increased for those with extravesical disease (HR 1.91; p<0.001 and HR 1.97; p<0.001). The 5- and 10-year RFS rates were 69% and 61%, respectively, and the 5- and 10-year OS rates were 64% and 44%.

**Comment:** Minimally-invasive radical cystectomy has gained traction as a standard of care surgical approach in bladder cancer over the last decade. While the procedure does have a steep learning curve, many studies including randomised trials have demonstrated benefit, specifically in regard to perioperative outcomes, with less blood loss, lower transfusion rates and potentially shorter lengths of stay. This study looked at long-term data after robot-assisted radical cystectomy. 51% of the 510 patients in this study underwent continent diversion. 31% of patients had a recurrence of bladder cancer and 23% died of bladder cancer. 3.5% of the patients had peritoneal carcinomatosis, which is lower than described previously by Nguyen et al. in 2015. The RFS and OS rates following robot-assisted radical cystectomy were comparable to the contemporary survival rates in literature following open radical cystectomy.

***Reference: Urol Oncol. 2025;43(4):267.e19–27***
Abstract


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## Intravesical instillation of chemotherapy before radical surgery for upper urinary tract urothelial carcinoma: the REBACARE trial

**Authors:** van Doeveren T et al.

**Summary:** In the prospective, single-arm, phase 2 REBACARE trial, 190 chemotherapy-naïve patients with primary upper urinary tract urothelial carcinoma were administered a single pre-operative intravesical instillation of mitomycin C within 3 hrs of surgery. At 2 years, the rate of intravesical recurrence (primary outcome) was 24% (95% CI 18–31), which fell below the pre-specified reduction target rate of >40%. Patients in the REBACARE study who had not received a prior diagnostic ureteroscopy had a significantly reduced risk of intravesical recurrence with pre-operative mitomycin C in comparison to a historic cohort of patients with upper-tract urothelial cancer who had not received pre-operative mitomycin C (HR 0.33; 95% CI 0.12–0.87). The rate of compliance with pre-operative mitomycin C instillation was 96%. There were no grade >2 AEs.

**Comment:** An adjuvant single instillation of mitomycin C following radical nephroureterectomy represents standard of care, as this has been shown to reduce the rate of intravesical recurrences. However, adoption of this strategy in clinical practice is hampered by concerns over extravesical chemotherapy leakage after bladder cuff excision, which can lead to severe morbidity and even mortality. The REBACARE trial explored the use of a pre-operative instillation of mitomycin C as a strategy to reduce the intravesical recurrence rate for bladder cancer. Although the prespecified reduction of >40% in the 2-year intravesical recurrence rate was not achieved, a significant reduction was observed in the group of patients who had not undergone a diagnostic ureteroscopy during workup for upper-tract urothelial cancer. Therefore, a single pre-operative mitomycin C instillation could be a viable strategy for this subgroup of patients. The study demonstrated a near-100% compliance rate with this strategy. The study also recommended judicious use of diagnostic ureteroscopy in the evaluation of upper-tract urothelial cancer, given the 5-fold higher rate of intravesical recurrence.

***Reference: Eur Urol. 2025;87(4):444–52***
Abstract

## The financial burden of localized and metastatic bladder cancer

**Authors:** Scilipoti P et al.

**Summary:** This systematic review of 73 studies assessed the financial burden of bladder cancer from both patient and healthcare perspectives. The key findings were that non-MIBC generated substantial costs for treatment and surveillance, and high-risk non-MIBC patients who progressed after bacillus Calmette-Guérin incurred expenses of >$200,000 after 5 years, through a combination of physician, inpatient and outpatient costs. MIBC patients incurred surgical costs of $30,000–$40,000, with increased costs in the advent of complications. There were greater costs with trimodal therapy (1-year management >$200,000) versus radical cystectomy due to medication, radiology and outpatient expenses. The greatest financial burden was seen in metastatic bladder cancer, as the costs for each 5-cycle course of systemic therapy ranged from $40,000 to >$100,000, with additional costs for supportive care, toxicities and combination therapies. There was a high prevalence of financial toxicity among minority populations, younger patients and those with lower levels of education.

**Comment:** This study highlights the financial toxicity of bladder cancer. Advanced bladder cancer incurs the highest costs, in view of the costs associated with systemic therapy and the management of AEs. The study also highlights the significant costs associated with surveillance of non-MIBC. Interestingly, the paper found that overall costs were higher with trimodal therapy when compared to radical cystectomy for non-metastatic MIBC. The study looks at costs from a European perspective and recognises that practice patterns and costs differ between countries. The paper also discusses strategies that could be used in clinical practice to mitigate the financial toxicity with a focus on early detection, optimising follow-up protocols based on risk stratification, avoiding extended lymph-nodal dissection in patients who would not benefit from it during radical cystectomy, and implementing value-based pricing models for patients with metastatic bladder cancer.

***Reference: Eur Urol. 2025;87(5):536–50***
Abstract

## Long-term quality of life in patients with bladder cancer following radical cystectomy

**Authors:** Akdemir E et al.

**Summary:** To examine the long-term QoL outcomes after radical cystectomy in patients with bladder cancer, these Dutch researchers invited patients to complete QoL questionnaires every 3 months in the first year, and then every year, for up to 8 years. Among 278 patients, emotional functioning scores increased over time, from 83.7 immediately after surgery to 90.1 at 8 years, reaching a similar level to a matched normative population. In contrast, physical functioning and QoL summary scores were lower than the normative population at 8 years. Patients with ASA scores of 2 or 3 had significantly lower post-surgical physical functioning scores than those with a score of 1 (MD –8 and –22, respectively; p<0.001), with lower emotional functioning scores (MD –1 and –11; p=0.5 and p<0.01) and lower QoL summary scores (MD –2 and –9; p=0.2 and p<0.01). The trajectory of QoL summary scores over time was worse for those with higher ASA scores (p=0.001), while the trajectory of physical functioning scores was worse for older patients (p<0.001).

**Comment:** The study gives us a real-world insight into the long-term QoL outcomes following radical cystectomy. The study looked at various domains in the QoL questionnaires with a focus on physical functioning, emotional functioning and QoL summary scores over an 8-year period. The study demonstrated that comorbid patients with higher ASA scores were more likely to have lower physical functioning, emotional functioning and QoL summary scores, emphasising the need for appropriate patient selection and counseling prior to radical cystectomy.

***Reference: BJU Int. 2025;135(4):675–83***
Abstract

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