



Validation of BIAS and IBCG criteria for predicting high-grade recurrence in low-grade NMIBC eligible for active surveillance

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Abstract

Purpose We evaluated the performance of two scoring systems—the Bladder Cancer Italian Active Surveillance (BIAS) criteria and the International Bladder Cancer Group (IBCG) score—for predicting high-grade (HG) disease at recurrence in patients with primary low-grade (LG) non-muscle-invasive bladder cancer eligible for active surveillance (AS).

Methods We retrospectively included patients with primary LG-NMIBC (2013–2022), eligible for AS according to BIAS criteria at time of diagnosis. All subsequent recurrences were managed with TURBT, allowing histopathological confirmation of tumor grade across 383 recurrences. Clinical data necessary to assess IBCG criteria and adherence to BIAS protocol were systematically collected at each recurrence, and their diagnostic performance in predicting HG progression was evaluated using C-statistics. Multivariable logistic regression was used to assess which individual BIAS and IBCG criteria were most predictive of progression.

Results At a median (IQR) follow-up of 55 (18–83) months, HG progression occurred in 45/383 (12%) of recurrences. BIAS criteria were met in 59% (226/383) of recurrences, of which 5.3% showed upgrading to HG. Conversely, only 16% (62/383) of recurrences had 0 IBCG risk factors, of which 8 (13%) upgraded. BIAS showed higher discriminative ability than IBCG (C-statistics 0.68 vs. 0.47, $p < 0.001$) and higher negative predictive value (95% vs. 87%).

Conclusion In patients with primary LG-NMIBC initially eligible for AS, adherence to BIAS criteria at recurrence identifies a subgroup with a lower prevalence of HG disease at immediate TURBT and may help inform shared decision-making regarding surveillance versus immediate intervention.

Keywords Urinary bladder neoplasms · Active surveillance · International Bladder Cancer Group · Non-muscle-invasive bladder neoplasms

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Introduction

The European Association of Urology (EAU) intermediate-risk (IR) represents the largest risk category for non-muscle-invasive bladder cancer (NMIBC), accounting for approximately 40–60% of all diagnoses. Although this group encompasses a wide spectrum of disease, high-grade tumors constitute the majority [1, 2]. While their risk of progression is generally low, the high rate of recurrence poses a clinical challenge, particularly in balancing oncological safety against overtreatment [3, 4]. Consequently, strategies such as active surveillance (AS) have been proposed for a selected subset of patients who might benefit from treatment de-intensification, aimed at reducing both healthcare costs and the morbidity associated with repeated transurethral resections of bladder tumors (TURBT) [5–7]. However, identifying which patients are suitable for each management strategy is still under study. In the efforts of further better stratifying this risk class, the International Bladder Cancer Group (IBCG) has developed a novel scoring system based on a cumulative number of risk factors, including multifocality, tumor size (≥ 3 cm), early recurrence (< 1 year), frequent recurrence (more than once per year), and recurrence despite prior adjuvant intravesical treatment [8]. Following IBCG recommendations, patients with IR-NMIBC, negative cytology and few risk factors (0–1) should be considered for an AS regimen, consisting of close monitoring to avoid immediate transurethral resection of a bladder tumor (TURBT) [9, 10]. Another seminal project conducted by the Bladder Cancer Italian Active Surveillance (BIAS) group has shown that well-selected patients can safely avoid or postpone surgery in the absence of five risk factors: negative urinary cytology, presence of ≤ 5 lesions with a diameter of ≤ 1 cm, absence of carcinoma in situ (CIS), or persistent gross haematuria [11, 12]. Despite these promising results, evidence supporting AS remains limited to small prospective and pilot cohorts, and long-term oncologic outcomes are still lacking. To further validate these risk criteria, we retrospectively collected data from a cohort of primary low-grade (LG) NMIBCs who were initially eligible for AS according to BIAS criteria. We then tested the performance of BIAS and IBCG scoring systems in predicting high-grade (HG) progression at each recurrence.

Patients and methods

Study population

Our Institutional IRB-approved database was queried to identify patients with a primary diagnosis of LG-NMIBC

between 2013 and 2022. We restricted our cohort to patients who were already eligible for AS at initial diagnosis, according to BIAS criteria (absence of hematuria, ≤ 5 tumors, largest diameter ≤ 1 cm, negative urinary cytology) [12]. This approach was adopted to exclude patients with a higher disease burden at presentation—such as larger tumors (≥ 3 cm) or multifocal disease—which may be classified as a high-risk profile according to EAU criteria (e.g., in the presence of additional risk factors such as age > 75 years and multifocality), and who would therefore not be ideal candidates for AS. Among these patients, we included only those who experienced at least one recurrence and subsequently underwent TURBT, allowing histopathological validation of tumor stage and grade at each event. Our final selection yielded a cohort of 155 patients (see Supplementary Table 1). Patients with unavailable key clinical or pathological data or insufficient follow-up were excluded during cohort selection.

Variables

The following variables were recorded and abstracted at T0 (diagnosis) for all patients: age, sex (male, female), presence of hematuria, maximum tumor size (cm), number of tumors, tumor stage (T) and grade (LG, HG). All patients underwent urinary cytology before TURBT and data on early intravesical treatments were also recorded at diagnosis. Following EAU recommendations, all patients underwent follow-up with cystoscopies and urinary cytology at 3 and 12 months after diagnosis, then yearly for 5 years [1]. The same aforementioned clinical and pathological variables were collected at time of each recurrence, allowing the assessment of IBCG score and adherence to BIAS criteria at each event. Tumor stage was defined according to TNM classification, while tumor grade was based on 2004/2016 World Health Organization classification [13]. All specimens from diagnosis to subsequent recurrences were analyzed by a dedicated uropathologist (F.S.). No independent secondary pathological review was performed.

Outcomes

For the purpose of this study, recurrence was defined as any cystoscopically suspected recurrent bladder lesion identified during follow-up and subsequently managed with TURBT, irrespective of the final histopathological result. The primary outcome was tumor upgrade to HG disease at recurrence. Follow-up was defined from the first recurrence to HG or last follow-up for patients free from upgrading; for each individual patient, TURBTs performed after the first occurrence of HG disease were not included in the analysis. To evaluate the performance of the two scoring systems, IBCG risk score and presence of any BIAS criteria were assessed at each

recurrence (see Supplementary Table 2 for detailed criteria) [9, 12]. For BIAS criteria, the presence of carcinoma in situ (CIS) was considered a HG disease and therefore was not evaluated among other BIAS criteria. IBCG variables were assessed dynamically at each recurrence using only clinical information available up to that event. Early recurrence was defined as a recurrence occurring within 12 months of the preceding TURBT. For the first recurrence, the interval was calculated from the index TURBT at initial diagnosis. Frequent recurrence ($> 1/\text{year}$) was determined from the recurrence history available up to the evaluated event, without using subsequent recurrence information. Intra-vesical treatment failure was defined according to prior intra-vesical treatment administered between the preceding TURBT and the evaluated recurrence, including postoperative single instillation where applicable.

Statistical analysis

The primary objective of our study was to evaluate the diagnostic performance of the two scoring systems in predicting the presence of HG disease at recurrence. For patients experiencing multiple recurrences, each recurrence was counted separately and the two scoring systems were assessed at each event.

For the BIAS criteria, diagnostic performance was assessed when all criteria were fulfilled as defined in the original active surveillance protocol [12]. In the IBCG model, diagnostic performance was assessed using the absence of any risk factors as the analytical threshold. Although the original recommendation suggests that AS may be considered in selected patients with 0–1 risk factors [4], we deliberately selected 0 risk factors to represent the most stringent and lowest-risk IBCG category. This approach allowed evaluation of the IBCG model under its most conservative definition and is consistent with previous studies in the active surveillance setting [16, 17]. Additionally, performance was assessed when both scoring systems were simultaneously satisfied.

Performance was assessed in terms of sensitivity, specificity, and positive and negative predictive values (PPV and NPV). To account for correlation among multiple recurrences from the same patient, 95% confidence intervals were estimated using a non-parametric patient-level cluster bootstrap with 5000 replicates. The discriminative ability of BIAS, IBCG, and their combination was evaluated using concordance statistics (C-statistics), pairwise comparisons between C-statistics were performed using the same paired patient-level cluster-bootstrap procedure, reported with 95% confidence interval (CI) [14]. For each bootstrap replicate, the difference in C-statistics between the two models under comparison was calculated. Two-sided p-values were obtained from the centered bootstrap distribution of

the difference in C-statistics. Multivariable logistic regression analysis was then performed to assess which of the single BIAS and IBCG criteria were independent predictors of progression. Because multiple recurrences could arise from the same patient, Huber–White robust standard errors clustered at the patient level were used to calculate 95% confidence intervals and p-values, using the cluster-robust variance–covariance matrix.

Baseline descriptive characteristics were summarized using medians and interquartile ranges (IQR) for continuous variables, while frequencies and proportions were used for categorical variables. All statistical analyses were two-sided, and a p -value < 0.05 was considered statistically significant. Analyses were performed using R software (version 4.2.3; R Foundation for Statistical Computing, Vienna, Austria).

Results

Overall, we included 155 primary LG-NMIBC initially eligible for AS for a total of 383 recurrences. Descriptive statistics for any recurrences is reported in Supplementary Table 3. Median follow-up for patients without progression was 55 (18–83) months. HG progression occurred in 45 recurrences (12%).

Figure 1 reported adherence rates to BIAS criteria and number of IBCG risk factors, stratified for HG progression. Overall, BIAS criteria were met in 226/383 (59%) of recurrences, while 62/383 (16%) had 0 IBCG risk factor. Progression to HG disease occurred in 12/226 cases (5.3%) when BIAS criteria were met, versus 33/157 (21%) when they were not. Conversely, progression to HG occurred in 8/62 (13%) of recurrences with no IBCG criteria, versus 37/321 (12%) of those who had at least 1 risk factor. Among the 45 HG upgrades, 33 (73%) did not meet all BIAS criteria, whereas 37 (82%) had at least one IBCG risk factor. When the two models were combined,

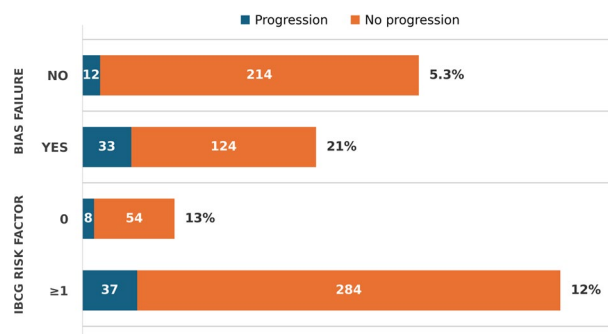


Fig. 1 Adherence to Bladder Italian Active Surveillance (BIAS) and International Bladder Cancer Group (IBCG) criteria based on progression to High-Grade Non-Muscle-Invasive Bladder Cancer at recurrence

Table 1 Performance and concordance analysis of the bladder Italian active surveillance and international bladder cancer group (IBCG) criteria in predicting high-grade progression at recurrence

AS criteria	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	C-statistics (95% CI)	p-value (vs. BIAS)	p-value (vs. IBCG)
BIAS failure	73 (60–86)	63 (58–69)	21 (15–28)	95 (91–97)	0.68 (0.61–0.75)	Ref	–
IBCG ≥ 1	82 (74–94)	16 (13–21)	12 (8.3–17)	87 (78–95)	0.47 (0.39–0.55)	<0.001	Ref
BIAS failure and/or IBCG ≥ 1	96 (85–99)	12 (8.7–16)	13 (9.3–17)	95 (84–99)	0.54 (0.50–0.57)	<0.001	0.08

Table 2 Multivariable logistic regression on high-grade progression for BIAS criteria

Bladder Italian active surveillance (BIAS) criteria		
Criterion	OR (95% CI)	p-value
Tumor size: >1 cm	4.97 (1.73–13)	0.04
Nr of tumors > 5	3.30 (1.72–6.43)	<0.001
Hematuria	5.01 (0.59–58)	0.13
Positive urinary cytology	NA*	NA*

*Positive urinary cytology was observed in only three recurrence events, all of which were associated with HG progression, resulting in complete separation and therefore reported as non-estimable odd ratio

Table 3 Multivariable Logistic Regression on High-Grade Progression for IBCG Criteria

International bladder cancer group (IBCG) criteria		
Criterion	OR (95% CI)	P-value
Failure to Intravesical Therapy	1.74 (0.56–5.42)	0.33
Early recurrence (< 12 months)	1.54 (0.72–3.22)	0.25
Frequent Recurrence (> 1/year)	2.97 (1.17–7.57)	0.02
Multiple tumors	1.16 (0–59.2.27)	0.65
Tumor size ≥ 3 cm	4.93 (1.12–22)	0.04

HG disease was found in 2/42 (4.8%) recurrences who met both IBCG and BIAS criteria, while 43/45 (96%) of overall upgrades had failed BIAS or had at least one IBCG criterion. The complete pathological distribution of recurrence according to BIAS and IBCG criteria is reported in Supplementary Table 4.

BIAS failure showed the highest negative predictive value (NPV 95%, 95% CI 91–97) compared with IBCG (NPV 87%, 95% CI 77–93). The combined rule (BIAS failure and/or ≥ 1 IBCG risk criterion) achieved the highest sensitivity (96%) with an NPV of 95% (Table 1).

BIAS criteria demonstrated greater discriminative ability for predicting progression (C-statistics: 0.68, 95% CI: 0.61–0.75) than both the IBCG scoring system (C-statistics: 0.47, 95% CI: 0.39–0.55; $p < 0.001$) and the combined model (C-statistics: 0.54, 95% CI: 0.50–0.57; $p = 0.08$; Table 1). Diagnostic performance restricted to the first recurrence per patient showed similar trend (see Supplementary Table 5).

Among BIAS criteria, both having more than 5 lesions (OR: 3.30, 95% CI: 1.72–6.43, $p < 0.001$) or >1 cm tumor (OR: 4.97, 95% CI: 1.73–6.43, $p = 0.04$) were associated with higher OR for upgrade (see Table 2). In IBCG scoring system, tumor size ≥ 3 cm (OR: 4.93, 95% CI: 1.12–22, $p = 0.04$) and more than 1 recurrence per year (OR: 2.97, 95% CI: 1.17–7.57, $p = 0.02$) were independent predictors of further developing HG disease (see Table 3).

Discussion

The present study evaluated the performance of two proposed risk-stratification tools, the BIAS criteria and the IBCG scoring system, in predicting the presence of high-grade (HG) disease at recurrence among patients with primary LG-NMIBC initially eligible for active surveillance (AS). Our aim was to assess their ability to safely identify patients suitable for conservative management and to explore their respective clinical utility in this setting.

Several key findings emerged from our analysis. First, the proportion of recurrences meeting criteria for continued AS differed substantially between the two models, with important clinical implications. Using BIAS criteria, approximately 59% of recurrences (226/383) remained eligible for surveillance, compared to only 16% (62/383) when applying IBCG (0 risk factors). This suggests that BIAS would allow a significantly larger proportion of patients to be considered for a discussion regarding surveillance rather than immediate TURBT.

Second, despite selecting a larger proportion of patients for surveillance, BIAS criteria were associated with a lower rate of HG progression among those deemed suitable for AS. Progression occurred in 5.3% of cases meeting BIAS criteria, compared to 13% among those with no IBCG risk factors. From a clinical perspective, BIAS appears to better address the key challenge of active surveillance: maximizing the number of patients who can

remain under surveillance while minimizing the risk of HG disease.

Third, combining the two models did not translate into meaningful clinical benefit in terms of patient selection, as it dramatically reduced the number of patients eligible for AS (42 cases), with only a marginal reduction in progression events (4.8% vs. 5.3% with BIAS alone). Fourth, our analysis of individual risk factors revealed that, within BIAS model, clinicopathological features, particularly tumor number and size, emerged as the strongest predictors of progression. Conversely, IBCG model revealed that other dynamic variables, such as recurrence frequency, played a more prominent role. Therefore, an integrated model incorporating both dimensions, tumor characteristics (number and size) and recurrence dynamics (frequency and timing), may provide improved risk stratification compared to either approach alone.

Our findings can be contextualized with the seminal prospective experience of the BIAS group, which remains the main reference for AS in this setting. In that study, BIAS failure occurred in 52% of recurrences, with HG or invasive progression observed in approximately 10% of failed cases [11]. In our cohort, we observed a slightly lower rate of failure (41%), but a higher proportion of HG progression among failures (21%). Despite this difference, our findings confirmed BIAS score accurately capture a population with a significantly higher risk of progression, while potentially allowing a larger proportion of recurrences to remain under surveillance. Moreover, in our series, progression remained relatively low among those meeting BIAS criteria (5.3%), supporting the potential value of these criteria in informing the discussion regarding continued surveillance rather than directly determining management. The role of the IBCG scoring system in the setting of active surveillance has been previously supported as a predictor of AS discontinuation and the subsequent need of TURBT [15]. Our findings suggest that its performance is more limited when the objective shifts from predicting treatment decision to identifying true oncological progression at each recurrence. Indeed, the risk of HG progression was not negligible among patients with no IBCG risk factors (13%) and was comparable to that observed in patients with at least one risk factor (12%). At the same time, the IBCG model demonstrated higher sensitivity, as 8% of patients who progressed had at least one risk factor, compared to 73% captured by BIAS failure. This suggests that, while IBCG may not be sufficiently accurate to define a “safe” subgroup for continued surveillance, it remains effective in identifying patients at higher overall risk of progression. From a clinical standpoint, these findings support a complementary role for IBCG as an additional source of risk information within an

individualized decision-making process for closer monitoring [16, 17].

Several limitations of our study should be acknowledged. First, although all patients were initially eligible for AS, they ultimately underwent TURBT at each recurrence and did not follow a true AS protocol. Consequently, our findings should not be interpreted as a direct evidence of the safety or efficacy of delaying intervention under AS, but rather as an assessment of the ability of these criteria to identify recurrences associated with a lower probability of histologically confirmed HG disease. Second, the retrospective design inherently introduces a risk of selection bias despite the use of a prospectively maintained institutional database. Specifically, the inclusion of patients exclusively with systematically histopathological confirmation at recurrence may have led to an overestimation of progression rates. This is particularly relevant when interpreting NPV, which is prevalence-dependent and may vary across cohorts with different underlying prevalence of HG disease. Moreover, our analysis was performed at the level of individual recurrences rather than patients, potentially introducing intra-patient correlation that was not fully accounted for and may affect the independence of observations. Third, because HG disease represented the primary outcome, the accuracy and reproducibility of pathological grading are particularly relevant. Although all specimens were evaluated by a dedicated uropathologist, no independent secondary pathological review was performed. Therefore, inter-observer variability in distinguishing LG from HG disease, particularly in borderline lesions, cannot be excluded and may have resulted in misclassification of the primary endpoint. Lastly, our cohort was derived from a single tertiary referral center, which may reflect specific clinical practices and patient selection, thus limiting the external applicability of our findings. Longer follow-up and prospective evidence are needed to assess more robust oncological endpoints, including cancer-specific survival. Finally, while current criteria rely on clinicopathological features, emerging evidence suggests that biomarkers may help identify biologically aggressive disease that is not captured by conventional risk factors. In this setting, biomarkers have shown higher sensitivity than cytology and may serve as complementary to clinical models, such as BIAS and IBCG, to refine risk stratification at diagnosis and dynamically during follow-up [12, 18].

Conclusions

In patients with primary LG-NMIBC initially eligible for AS, adherence to BIAS criteria at recurrence identified a subgroup with a lower prevalence of HG disease at immediate TURBT and may help inform shared decision-making regarding surveillance versus immediate intervention.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s11255-026-05411-x>.

Author contributions Marco Finati: Project development/protocol, data collection and management, data analysis, and manuscript writing. Nicola Schiavone, Anna Ricapito, Nicola d'Altia, Antonio Fanelli, and Nicolò Giannoccaro: Data collection and management, and investigation. Ugo Falagario and Francesca Sanguedolce: Data analysis. Roberto Contieri, Savio Pandolfo, Rocco Damiano, Richard Naspro, and Marco Roscigno: Manuscript editing. Luigi Filippo Da Pozzo, Luigi Cormio, Carlo Bettocchi, Gian Maria Busetto, and Giuseppe Carrieri: Supervision. Benjamin Pradère: Project development/protocol, manuscript writing.

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Data availability Data will be made available upon request in compliance with our Institution and IRB regulations.

Declarations

Approval of the research protocol by an Institutional Reviewer Board The study was approved by the Ethical Committee of Policlinico Riuniti di Foggia on March 15, 2022 (Approval Code 31/CE/2022).

Conflicts of interest None of the authors have any relevant disclosures, and none of the authors have any financial or non-financial interests that may be relevant to the submitted work.

Informed consent An institutional waiver of informed consent was granted due to the retrospective nature of the registry.

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