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Research Article

Patient-Reported Toxicity During BCG Therapy for NMIBC: A Descriptive Study Using a Structured Self-Questionnaire

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Abstract

Purpose: Bacillus Calmette-Guérin (BCG) therapy remains the standard treatment for intermediate- and high-risk Non–Muscle-Invasive Bladder Cancer (NMIBC), but its tolerability remains a major concern. Conventional clinician-reported toxicity grading may underestimate patient symptom burden. This study aimed to describe the frequency, severity, and trajectory of BCG-related adverse events using a structured weekly self-assessment questionnaire.

Methods: In this retrospective, monocentric study, BCG-naive NMIBC patients completed a standardized paper-based questionnaire daily for 7 days after each BCG instillation. The instrument captured 13 predefined symptoms (local and systemic), each graded on a 3-point severity scale. Composite scores (mean, sum, and symptom count) were calculated for each instillation. Data were analyzed descriptively and stratified by treatment phase (induction, consolidation, maintenance).

Results: A total of 293 patients completed 4892 BCG instillations. Local symptoms, particularly pollakiuria, urgency, and dysuria, were the most prevalent and intensified over time. Systemic symptoms (e.g., fatigue, fever, myalgia) were less frequent and remained relatively stable. Composite symptom scores correlated well with toxicity grading and showed good discriminative ability for high-grade adverse events (AUC up to 0.84 for local toxicity). The symptom count (≥2 symptoms rated ≥2) emerged as the most predictive score.

Conclusion: A structured self-reported symptom questionnaire allows a dynamic and granular assessment of BCG-related toxicity. Our findings support the integration of patient-reported outcomes into routine NMIBC care to better detect, monitor, and potentially prevent adverse events.

Keywords: BCG Therapy; NMIBC; Patient-Reported Outcomes; Self-Questionnaire; Toxicity

Introduction

Bladder cancer is the fifth most common malignancy in men, with an estimated 2.5 million cases diagnosed annually worldwide [1]. In approximately 70–80% of cases, the disease presents as a non–muscle-invasive bladder cancer (NMIBC) at diagnosis. Intravesical Bacillus Calmette-Guérin (BCG) remains the standard adjuvant treatment for patients with intermediate- and high-risk NMIBC, when followed by at least one year of maintenance therapy[2-4]. While BCG therapy has demonstrated durable efficacy, its broader use is limited by supply shortages and toxicity. Up to 20% of patients experience grade III local or systemic adverse events, including BCGitis, and 5–10% may develop Serious Adverse Events (SAEs) requiring antituberculous treatment [5,6]. Historically, treatment completion rates have been suboptimal: in the pivotal Lamm trial, only 16% of patients completed the full maintenance protocol, while more recent EORTC studies report completion rates of 29–36% [7,8]. A key limitation of prior toxicity studies is their reliance on physician-reported adverse events, typically graded according to WHO or CTCAE criteria. These may underreport patient discomfort or fail to capture the dynamic nature of symptoms that fluctuate between instillations. Patient-Reported Outcomes (PROs), especially when collected prospectively and systematically, may offer a more sensitive and clinically relevant picture of treatment-related burden. A study by Saint et al. involving 72 patients receiving BCG therapy showed that a daily self-questionnaire could effectively predict premature treatment discontinuation [9]. However, such tools remain underutilized in routine clinical practice and are rarely standardized across centers. Traditional toxicity assessments during intravesical BCG therapy are typically performed retrospectively by clinicians, based on predefined criteria such as the WHO or CTCAE classifications.

These evaluations often occur at the end of each treatment phase (induction, consolidation, maintenance), using global scoring tools that may underrepresent the variability and temporal dynamics of patient symptoms. For example, the standard AFU (Association Française d'Urologie) toxicity form aggregates adverse events over an entire treatment cycle, potentially overlooking the fluctuating intensity and clustering of symptoms between instillations. Our institution developed a structured weekly auto-questionnaire to systematically capture both local and systemic symptoms as experienced by patients after each BCG instillation. This prospective, fine-grained monitoring allows for a more detailed assessment of symptom severity, duration, and frequency. We hypothesize that such a dynamic and patient-centered approach may provide a more accurate measure of treatment burden, enable the development of robust symptom grading models, and ultimately enhance the prediction of clinically significant outcomes such as treatment interruption or serious adverse events.

Recently, Rutherford et al. proposed a standardized PRO-based tool (the BCG Symptoms Index) to monitor patient-reported toxicity during BCG therapy and demonstrated its value for identifying temporal toxicity patterns [10]. Our approach differs in design and scope: rather than collecting one global score at each visit, our questionnaire allows daily symptom reporting over the week following each instillation, with both symptom-specific and composite severity scores. This design provides a richer understanding of patient experience across all phases of treatment and may offer improved predictive power.

Objective

In this descriptive study, we aim to characterize the frequency, nature, and timing of local and systemic symptoms reported by patients undergoing intravesical BCG therapy, using a structured weekly auto-questionnaire completed after each instillation. This analysis provides a detailed symptom profile across induction, consolidation, and maintenance phases, and sets the stage for future predictive modeling of toxicity-related treatment modifications.

Material and Methods

Inclusion and Exclusion Criteria

Eligible patients were those with a diagnosis of intermediate-risk Non–Muscle-Invasive Bladder Cancer (NMIBC), such as recurrent and/or multifocal pTa lesions, or high-risk NMIBC, including high-grade pTa or pT1 tumors and Carcinoma In Situ (CIS). All included patients were BCG-naive at the time of treatment initiation and had complete follow-up data available for the full BCG treatment course. Exclusion criteria comprised the presence of very-high-risk tumors—defined as pT1 high-grade with concomitant CIS, tumor size exceeding 3 cm, lymphovascular invasion, prostatic urethral involvement, or histological variants with aggressive behavior—as well as any prior history of intravesical BCG therapy or being lost to follow-up during the treatment period. The study received ethical clearance from the institutional review boards (CPP Rhone Alpes, Sud Est II, autorisation ERB 20-5344), ensuring adherence to ethical standards in accordance with the Declaration of Helsinky ().

Treatment

Intravesical BCG was administered according to the standard Lamm protocol (81 mg), comprising an induction phase (six weekly instillations), a consolidation phase of 3 weekly instillations at 6 weeks from the last instillation of the induction course, and a maintenance phase of three weekly instillations every 6 months.

Symptom Monitoring and Patient-Reported Questionnaire

A structured, paper-based self-assessment questionnaire was used to prospectively monitor BCG-related symptoms after each instillation. Patients were instructed to complete the questionnaire daily at home over the 7 days following each instillation. The self-

assessment instrument captured 13 predefined symptoms, grouped into two domains. Systemic symptoms included fatigue, muscle pain, joint pain, and fever, with the latter recorded both in terms of temperature (°C) and duration (in hours). Local urinary symptoms comprised urgency, burning during urination (dysuria), hematuria, frequency of nighttime urination (pollakiuria), incontinence on effort, post-void dribbling, straining to void, perineal pain, suprapubic pain, and constipation. For each symptom, patients were asked to indicate its presence or absence. If present, symptom severity was rated on a three-point scale: grade 1 (mild), grade 2 (moderate), and grade 3 (severe). Questionnaires were collected and reviewed weekly during follow-up visits by a trained urology nurse. Based on a predefined institutional algorithm ("ALFRESA"), a composite local toxicity score and systemic toxicity score were generated for each instillation (range: 1 to 4), reflecting the intensity and duration of reported symptoms. An example of the original questionnaire is presented in Figure 1.

Did you urinate at night? If yes, how many times ? G1= 1-2 G2= 2-4 G3= >4	Yes No D1 D2 D3 D4 D5 D6	**Did you have a fever (T° > 37.5°C)** G1= <38 G2= <38.5 G3= >38.5	Yes No D1 D2 D3 D4 D5 D6
Did you experience urgent urges to urinate? G1= lightly G2= mild G3= severely	Yes No D1 D2 D3 D4 D5 D6	**Did you experience muscle pain**? G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6
Did you notice blood in your urine? G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6	**Did you experience fatigue?** G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6
Did you experience burning during urination G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6	**Did you experience joint pain?** G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6
Did you experience dribbling at the end of urination? G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6	**Did you experience abnormal constipation?** G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6
Did you experience leakage during physical effort ? G1= lightly G2= mild G3= severly	Oui Non D1 D2 D3 D4 D5 D6	**Did you experience perineal pain?** G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6

Did you have to strain to urinate satisfactorily? G1= lightly G2= mild G3= severly	Oui Non D1 D2 D3 D4 D5 D6	**Did you experience suprapubic pain?** G1= lightly G2= mild G3= severly	Yes No D1 D2 D3 D4 D5 D6

Figure 1: Weekly self-assessment questionnaire used to monitor BCG-related symptoms After each intravesical BCG instillation, patients completed a structured self-questionnaire to report the presence and severity of 13 symptoms over the 7 days following instillation. Each symptom was scored daily from Grade 1 (mild) to Grade 3 (severe). The questionnaire covered both systemic (e.g., fever, fatigue, muscle and joint pain) and local urinary symptoms (e.g., urgency, burning, hematuria, voiding difficulties). The responses were reviewed by a trained nurse at the following clinical visit and used to compute a local and systemic toxicity score for each instillation.

Weekly Monitoring Sheet

(Must be completed before starting and before each instillation)

Outcomes and Data Collection

The primary objective of the study was to characterize the frequency, type, and severity of both local and systemic symptoms associated with intravesical BCG treatment, using the weekly self-questionnaire.

The analysis focused on symptom variability across the three treatment phases:

Serious Adverse Events (SAEs), treatment discontinuation, and oncological outcomes (e.g., recurrence or progression) were prospectively collected in a secure institutional research database in compliance with EU General Data Protection Regulation (GDPR). However, these outcomes were not analyzed in the present study.

Statistical Analysis

All analyses were descriptive in nature.

- Categorical variables (e.g., presence of symptom, severity grade) were summarized using frequencies and percentages.
- Continuous variables (e.g., age, number of instillations) were described using medians and Interquartile Ranges (IQR).

Symptom prevalence was assessed globally and stratified by treatment phases. For each symptom, the proportion of BCG instillations reporting grade 2 (moderate) or grade 3 (severe) intensity was computed. Composite toxicity scores (local and systemic) were analyzed per instillation, and their distribution was explored across treatment phases. Visual representations included grouped bar plots, stacked histograms, and heatmaps to explore temporal patterns and clustering of toxicity. All statistical processing and figure generation were conducted using ©Stata 16 (Statacorp LLC, Texas, USA)

Results

A total of 293 patients who received intravesical BCG therapy for Non–Muscle-Invasive Bladder Cancer (NMIBC) were included in this study, contributing to a total of 4892 instillations analyzed. The median age of the patients was 72 years (interquartile range: 65–79 years), and 81.2% were male (n = 238) while 18.8% were female (n = 55), consistent with the known epidemiology of bladder cancer. Most patients underwent a standard treatment regimen comprising induction, consolidation, and/or maintenance phases. Among all instillations, 41.6% occurred during the induction phase, 20.9% during consolidation, and 37.5% during maintenance. The median number of instillations per patient was 15 (range: 6 to 27). We analyzed the severity of each symptom recorded after BCG instillations across the cohort (N = 4892 instillations). Using the structured weekly questionnaire, we quantified the proportion of instillations associated with moderate (Grade 2) and severe (Grade 3) symptoms. As shown in Figure 2, nocturia (PKc) emerged as the most prevalent clinically significant symptom, affecting approximately 16.3% of instillations at Grade 2 or higher. Urgency, fatigue, and burning micturition were also commonly reported, though with varying severity. Overall, most symptoms were more frequently rated as moderate (Grade 2), while Grade 3 events were less frequent but not negligible. These results underscore the heterogeneity and intensity of both local and systemic toxicities experienced during BCG therapy. Composite scores were calculated for each BCG instillation to summarize the intensity and burden of reported symptoms (Figure 3).

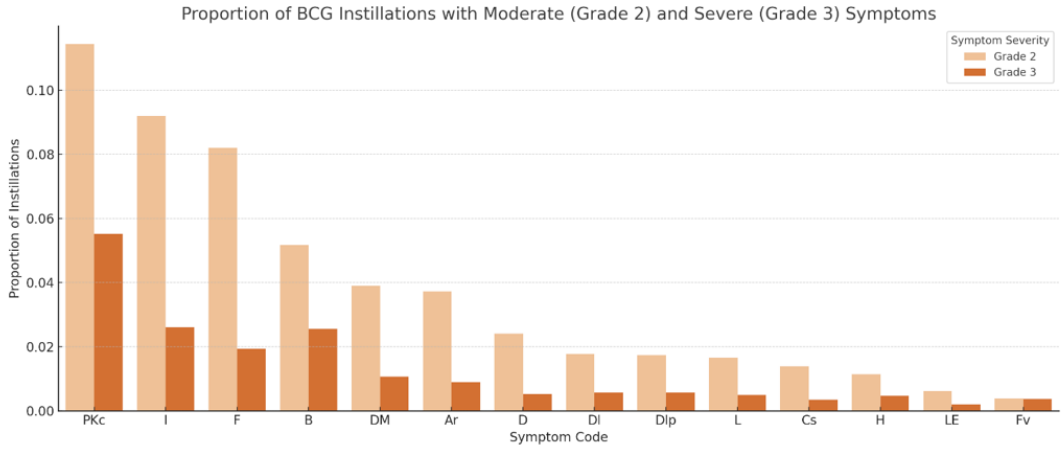

Figure 2 : Proportion of BCG instillations (N = 4892) associated with moderate (Grade 2) and severe (Grade 3) symptoms, stratified by symptom.

This histogram illustrates the symptom burden reported by patients using a structured weekly self-assessment questionnaire. Among all symptoms, **pollakiuria (PKc)** was the most frequently reported at clinically significant levels, followed by **urgency (I)**, **fatigue (F)**, and **burning during urination (B)**. Most symptoms were more commonly reported as **Grade 2** than **Grade 3**, while **severe symptoms** remained infrequent overall. Both **local** and **systemic** symptoms contributed to the treatment-related burden.

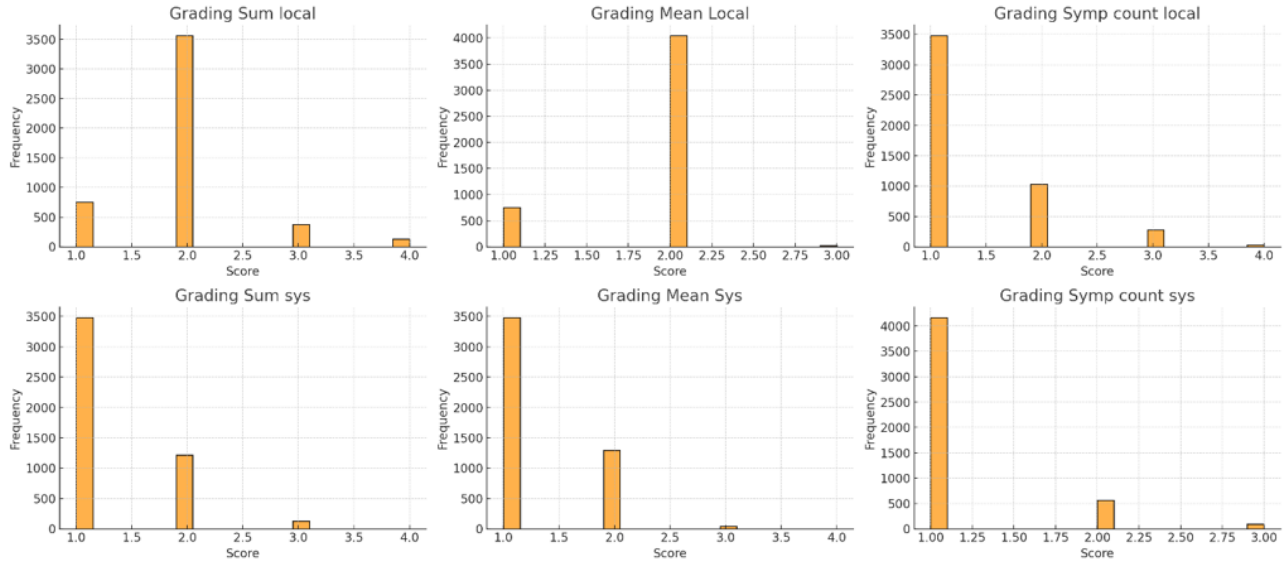

Figure 3: Distribution of Composite Symptom Scores for BCG Instillations.

Histograms display the distribution of six composite scores derived from a structured weekly self-assessment questionnaire, computed across 4,892 BCG instillations. Scores are grouped by symptom type (local or systemic) and include: (1) sum of symptom grades, (2) mean symptom grade, and (3) number of symptoms with grade ≥2 (moderate or severe). Local toxicity scores exhibit broader and higher distributions than systemic scores, reflecting the predominance of urinary over systemic symptoms during BCG therapy.

For local symptoms, the total sum score ranged from 0 to 20, with a peak between 3 and 6. Mean local scores were generally between 0.5 and 1.5, while the count of local symptoms graded ≥2 was 0 in 54.2% of instillations, 1–2 in 35.4%, and ≥3 in 10.4%. In contrast, systemic scores were lower overall: the mean systemic grade was <1 in over 90% of instillations, and for the majority, no systemic symptom ≥2. These patterns reflect a predominance of mild to moderate local urinary toxicity, particularly during early phases of BCG treatment. To assess the validity of our newly constructed composite symptom scores, we compared their distributions according to a binary toxicity grading system currently in use (0 = no toxicity, 1 = toxicity present). Six scores were computed: sum, mean, and symptom count (≥2) for both local and systemic domains. Summary statistics for each score by binary grade are provided in Table 1 (Annex). All scores showed higher means and medians in instillations labeled toxic, with clear separation illustrated in the boxplots (Figure 4).

Grading Sum local

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	752	1.000	0.000	1.000	1.000	1.000
1.000	2374	2.004	0.065	2.000	2.000	2.000
2.000	1086	2.171	0.425	2.000	2.000	2.000
3.000	613	2.723	0.746	3.000	2.000	3.000

Grading Mean Local

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	752	1.000	0.000	1.000	1.000	1.000
1.000	2374	2.000	0.000	2.000	2.000	2.000
2.000	1086	2.002	0.043	2.000	2.000	2.000
3.000	613	2.034	0.182	2.000	2.000	2.000

Grading Symp count local

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	752	1.000	0.000	1.000	1.000	1.000
1.000	2374	1.000	0.000	1.000	1.000	1.000
2.000	1086	1.747	0.591	2.000	1.000	2.000
3.000	613	2.418	0.573	2.000	2.000	3.000

Grading Sum sys

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	3484	1.000	0.000	1.000	1.000	1.000
1.000	685	2.000	0.000	2.000	2.000	2.000
2.000	505	2.107	0.309	2.000	2.000	2.000
3.000	151	2.503	0.528	2.000	2.000	3.000

Grading Mean Sys

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	3484	1.000	0.000	1.000	1.000	1.000
1.000	685	2.000	0.000	2.000	2.000	2.000
2.000	505	2.002	0.044	2.000	2.000	2.000
3.000	151	2.318	0.495	2.000	2.000	3.000

Grading Symp count sys

Toxicity_Grade	N	Mean	SD	Median	Q1	Q3
0.000	3484	1.000	0.000	1.000	1.000	1.000
1.000	685	1.000	0.000	1.000	1.000	1.000
2.000	505	2.105	0.307	2.000	2.000	2.000
3.000	151	2.258	0.439	2.000	2.000	3.000

Table 1: *Summary statistics of composite symptom scores by binary toxicity grade.* Each score is reported with mean, median, standard deviation, and interquartile range, stratified by local and systemic toxicity status (binary grading). This table supports the discriminative validity of composite scoring metrics.

Summary Statistics of Composite Symptom Scores by Binary Toxicity Grade

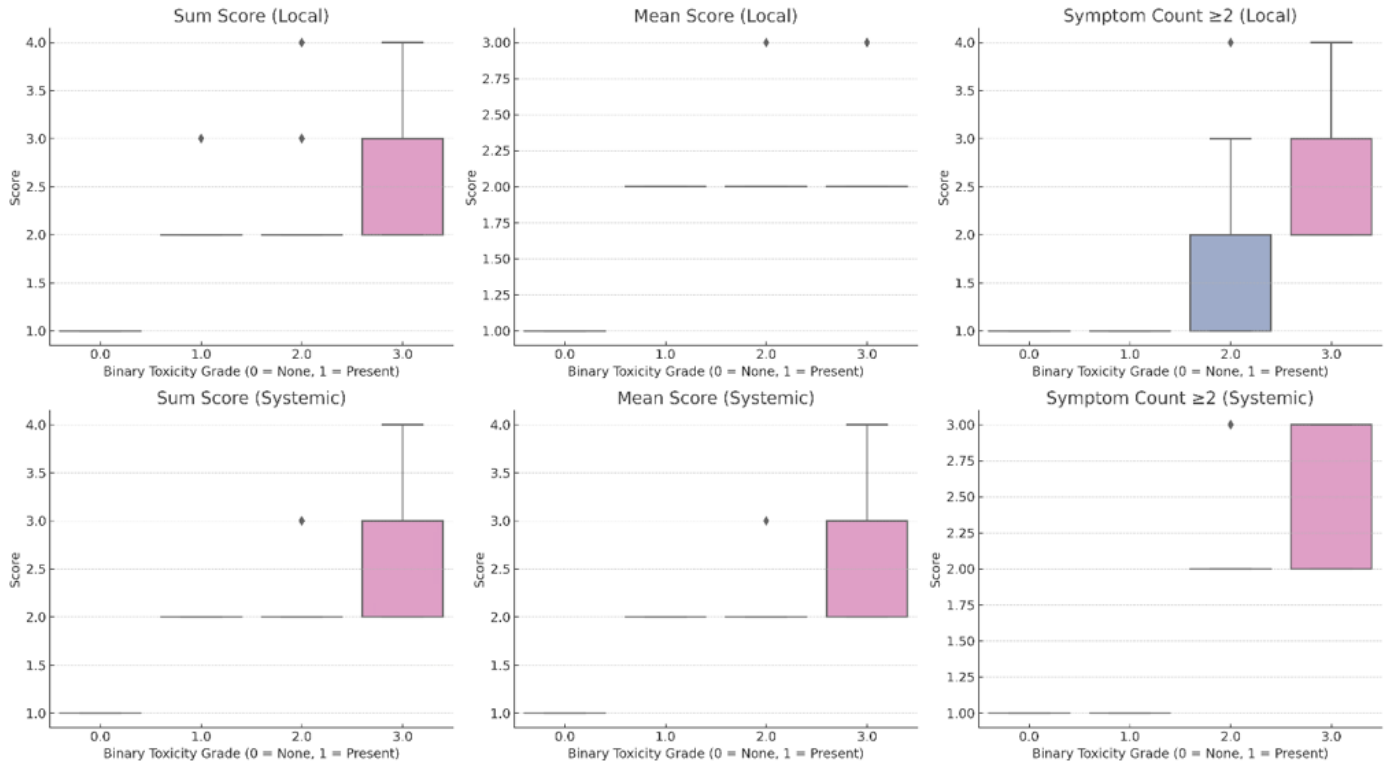

Figure 4: Distribution of composite symptom scores by binary toxicity grade. Boxplots represent six computed composite scores based on weekly symptom questionnaires during BCG instillations. Scores are compared between instillations classified as non-toxic (grade 0) versus toxic (grade 1) using binary toxicity grading. Top row shows local symptoms (sum, mean, and count), bottom row shows systemic symptoms. All scores demonstrate higher medians in toxic instillations.

These results support the utility of our composite scores in capturing symptom burden and distinguishing toxic instillations. This framework provides the basis for further predictive modeling of severe adverse events and treatment discontinuation. To evaluate the discriminative ability of our newly developed composite symptom scores, we performed ROC curve analyses using high-grade toxicity (defined as Grade ≥ 3) as the outcome, separately for local and systemic events (Figure 5 and 6). For local toxicity, the symptom count score (defined as ≥ 2 symptoms graded 2 or higher) demonstrated the highest predictive accuracy, with an AUC of 0.84, followed by the sum score (AUC = 0.80) and the mean score (AUC = 0.78). Similarly, in predicting systemic toxicity, the symptom count score again yielded the best performance (AUC = 0.81), with the sum and mean scores achieving AUCs of 0.78 and 0.75, respectively. These results highlight the value of structured, symptom-based composite scoring systems in capturing clinically significant treatment burden and identifying patients at risk for high-grade toxicity during intravesical BCG therapy. To explore temporal patterns of symptom burden across the BCG treatment course, we examined the distribution of composite symptom scores—mean score, sum score, and symptom count—for both local and systemic symptoms across the three defined treatment phases: induction, consolidation, and maintenance. As shown in Figure 7, local symptom scores progressively increased from induction to maintenance. The mean local score rose from 1.77 during induction to 1.93 during maintenance, and similar trends were observed for the sum score (1.85 to 2.09) and symptom count (1.26 to 1.44). This suggests a cumulative local toxicity burden over time. In contrast, systemic symptom scores remained relatively stable across phases, with only slight fluctuations in mean (1.28–1.31), sum (1.29–1.33), and symptom count (1.14–1.19), indicating that systemic side effects were more constant and less influenced by treatment duration or intensity.

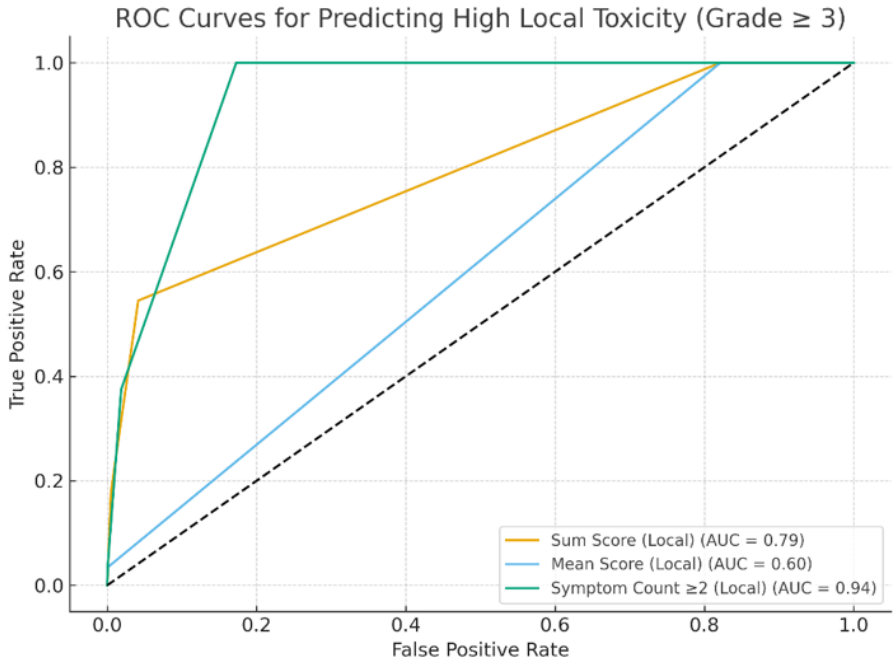

Figure 5: ROC curves for predicting high-grade local toxicity (Grade ≥ 3).

This figure shows receiver operating characteristic (ROC) curves evaluating the predictive performance of three composite symptom scores—sum score, mean score, and symptom count ≥ 2—for high-grade local toxicity following intravesical BCG instillation. High-grade toxicity was defined as a local toxicity grade of 3 or higher. The Area Under The Curve (AUC) was highest for the symptom count score (AUC = 0.84), followed by the sum score (AUC = 0.80) and the mean score (AUC = 0.78), indicating good discriminative ability.

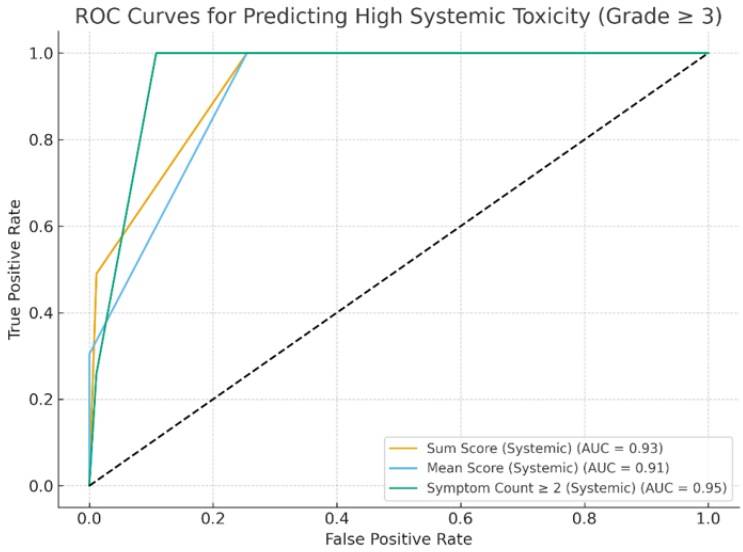

Figure 6: ROC curves for predicting high-grade systemic toxicity (Grade ≥ 3).

This figure displays receiver operating characteristic (ROC) curves assessing the ability of three composite scores—systemic sum score, mean score, and symptom count ≥ 2—to predict high-grade systemic toxicity following intravesical BCG therapy. The best discriminative performance was achieved by the symptom count score (AUC = 0.81), followed by the sum score (AUC = 0.78) and mean score (AUC = 0.75).

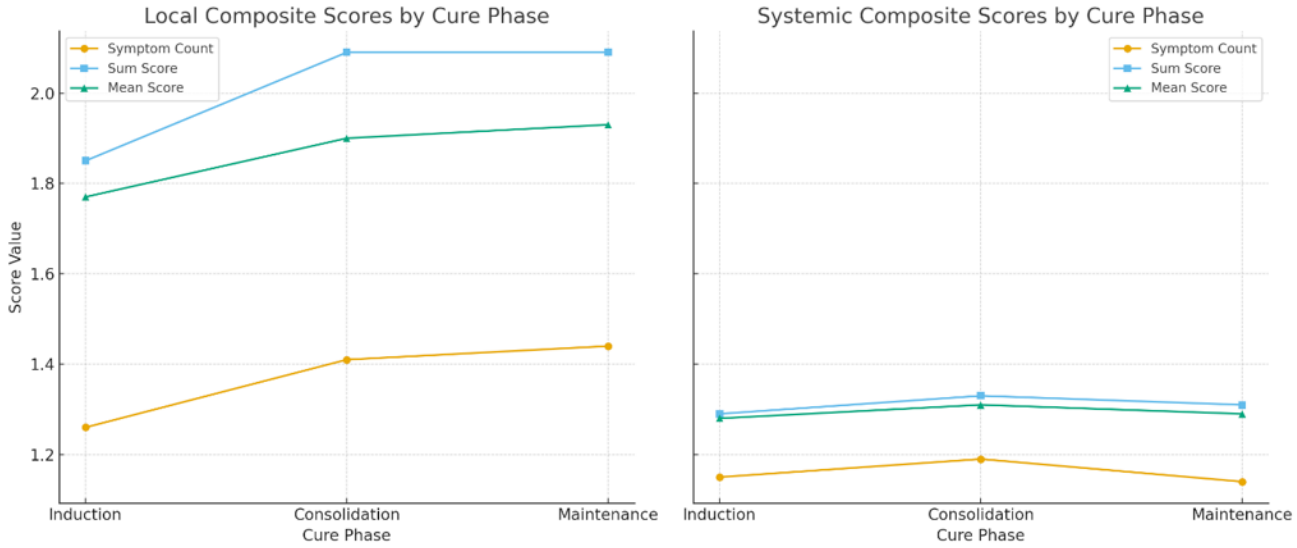

Figure 7: This figure shows the mean values of three composite scores (symptom count, sum score, and mean score) for local (left) and systemic (right) symptoms, stratified by BCG treatment phase. Local symptom scores show a progressive increase from induction to maintenance, suggesting accumulating local irritation over time. In contrast, systemic symptom scores remain relatively stable across treatment phases.

Discussion

This study provides a granular, patient-centered evaluation of intravesical BCG toxicity using a structured weekly self-assessment questionnaire. Unlike traditional clinician-reported grading systems, our methodology captures real-time symptom dynamics across instillations and treatment phases, yielding composite scores that had better reflect the patient's lived experience. Our data confirm that Lower Urinary Tract Symptoms (LUTS) dominate the toxicity profile of BCG therapy, while systemic symptoms, though less frequent, contribute meaningfully to treatment burden.

Positioning with in Existing Literature

Our work expands upon prior efforts to integrate Patient-Reported Outcomes (PROs) into BCG toxicity monitoring. While the AFU form and CTCAE remain widely used, they often aggregate symptoms over several weeks and lack temporal resolution. Rutherford et al. recently proposed a BCG-specific PRO tool—the BCG Symptoms Index—that demonstrated strong psychometric properties and temporal validity across treatment cycles [10]. However, their tool relies on global ratings per instillation, whereas our weekly questionnaire enables daily tracking of 13 local and systemic symptoms, offering greater sensitivity and granularity. Furthermore, our study is one of the few to implement such an instrument in a real world, routine care setting, across a large cohort of nearly 5,000 instillations. In line with the early work by Saint et al. [9], who showed that self-reported symptom scores could predict treatment discontinuation, our results reinforce the clinical value of systematically collected patient feedback. Our scoring system—comprising sum, mean, and symptom count metrics—provides a robust framework for assessing cumulative burden. These composite scores demonstrated excellent discriminative ability, particularly for identifying high-grade toxicity (AUC up to 0.84 for local symptoms and 0.81 for systemic symptoms). This supports their use as both a descriptive and predictive tool for future clinical research.

Interpretation and Clinical Implications

We observed a progressive increase in local toxicity scores across treatment phases, particularly from induction to maintenance. This trend suggests a cumulative irritative effect that may be exacerbated by ongoing immune activation or urothelial sensitization. In contrast, systemic symptoms remained relatively constant across time, implying a distinct underlying mechanism and potential for different management strategies. The high frequency of pollakiuria, urgency, and burning micturition is consistent with previous reports of BCG-induced cystitis [5,6]. However, our study goes further by distinguishing mild, moderate, and severe episodes and analyzing their evolution over time. This differentiation is clinically relevant: persistent moderate symptoms may be more disabling than isolated severe ones, a nuance that is often lost in binary toxicity frameworks. The ability of our composite scores to capture this complexity is a key strength. The "symptom count ≥2" metric, in particular, demonstrated superior discriminative performance and may serve as a practical threshold for clinical alerts or treatment adaptation. Importantly, these tools can be integrated into digital platforms, enabling remote monitoring and early intervention—especially valuable in frail or elderly populations.

Strengths and Limitations

The strengths of this study include its large sample size, systematic symptom tracking, and use of validated statistical tools. The self-questionnaire was implemented prospectively and reviewed weekly, ensuring high data quality and clinical relevance. Our analysis focused on descriptive accuracy and predictive validity, establishing a methodological foundation for future longitudinal studies. Nonetheless, certain limitations must be acknowledged. This was a monocentric study, and the scoring algorithm ("ALFRESA") used to compute composite grades was developed locally. External validation in independent cohorts is required. Moreover, we did not correlate symptom scores with clinical outcomes such as treatment discontinuation, serious adverse events, or quality of life, though such analyses are underway. Finally, some symptoms—such as constipation or perineal pain—may be influenced by patient comorbidities or medications, requiring careful interpretation.

Future Directions

The next step will be to validate these composite scores as predictors of clinically meaningful endpoints, including Serious Adverse Events (SAEs), BCG interruptions, and oncological outcomes. In addition, incorporating patient-level covariates such as age, sex, baseline urinary function, or psychological distress may further refine predictive models. Ultimately, the integration of structured PROs into BCG treatment workflows has the potential to enhance safety, personalize care, and improve adherence—goals that are increasingly important in NMIBC management.

Conclusion

Our study demonstrates that a structured, weekly self-assessment questionnaire can provide a more precise and dynamic evaluation of toxicity during intravesical BCG therapy. By capturing symptom severity and clustering across treatment phases, and by developing composite scores with strong discriminative power for high-grade toxicity, we offer a practical and patient-centered framework for toxicity monitoring. These findings support the integration of patient-reported outcomes into routine care for NMIBC and lay the groundwork for predictive models that can guide individualized treatment adaptation and improve patient safety.

Running title: Self-Reported Toxicity during BCG Therapy
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