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Understanding and Managing BCG-Related Adverse Effects in Bladder Cancer Patients: A Case series of 20 patients

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Abstract

Background: Intravesical Bacillus Calmette-Guérin (BCG) therapy is a key treatment for high-risk non-muscle invasive bladder cancer (NMIBC), effectively reducing recurrence and progression. However, BCG-induced adverse effects, particularly lower urinary tract symptoms (LUTS), can impact patient adherence and quality of life.

Objective: This study evaluates the prevalence, severity, and management of post-BCG complications, with a focus on LUTS, hematuria, and pain-related symptoms.

Methods: A retrospective analysis of 20 patients who received BCG therapy at the University Hospital Center Ibn Rochd, Casablanca, between 2023 and 2024 was conducted. Patient demographics, tumor characteristics, symptomatology, and treatment strategies were assessed.

Results: All patients (100%) developed LUTS, with pollakiuria (mean: 6.2 daytime and 7.8 nocturnal voids) and urgency being the most common. Dysuria affected 65%, hypogastric pain 60%, and hematuria 15%, though it was self-limited. No patients developed fever or systemic complications. Most (80%) achieved symptom resolution within two months, with corticosteroids and fluoroquinolones as primary treatments.

Conclusion: While BCG therapy remains essential for NMIBC, its side effects are nearly universal. Effective symptom management and patient education are crucial to ensuring adherence and optimizing treatment outcomes.

Keywords: BCG therapy; NMIBC; Lower urinary tract symptoms; Hematuria; Patient adherence

Introduction

Bladder cancer is the 10th most common malignancy worldwide, with non-muscle invasive bladder cancer (NMIBC) comprising approximately 70% of newly diagnosed cases [1]. Among patients with high-risk NMIBC, intravesical Bacillus Calmette-Guérin (BCG) therapy is widely used, demonstrating efficacy in reducing tumor recurrence and progression rates. However, despite its effectiveness, BCG therapy is frequently associated with adverse effects, including irritative lower urinary tract symptoms (LUTS), hematuria, fever, and, in rare cases, severe systemic BCG infections [2].

BCG-induced inflammation is an expected immune response, as the instillation stimulates a localized granulomatous reaction, activating T-helper cells and promoting anti-tumor immunity [3]. However, this same immune activation can lead to prolonged bladder irritation, resulting in pollakiuria, urgency, dysuria, and pelvic pain, which can significantly impact patient quality of life [4].

Although the incidence of BCG-related complications has been well-documented, data on real-world symptom burden, treatment responses, and patient outcomes remain limited, particularly in populations receiving standardized BCG protocols. This study presents a case series of 20 patients who developed post-BCG complications, focusing on symptomatology, management strategies, and clinical outcomes. By providing a detailed analysis of lower urinary tract symptoms, hematuria, and pain-related complications, we aim to contribute to the grow-

ing body of evidence on BCG-related side effects and their implications for clinical practice.

Methods

Study Design and Patient Selection

This retrospective case series examines patients who underwent intravesical Bacillus Calmette-Guérin (BCG) therapy for high-risk non–muscle-invasive bladder cancer (NMIBC) between 2023 and 2024 at Department of Urology, University Hospital Center Ibn Rochd Casablanca, Morocco.

Inclusion criteria:

- Adults (≥18 years) with a histologically confirmed diagnosis of high-risk NMIBC.
- Patients who completed at least one full induction course of BCG therapy (six weekly instillations).
- Patients who experienced at least one BCG-related complication during or after treatment.

Exclusion criteria:

- History of muscle-invasive bladder cancer (MIBC).
- Failure to complete a minimum of three BCG instillations.
- Pre-existing conditions that could interfere with symptom evaluation (e.g., chronic cystitis, radiation-induced cystitis).

Data Collection and Variables

Patient data were extracted from electronic records, including demographics, tumor characteristics, and BCG treatment protocols. Post-BCG symptoms and management strategies were analyzed, with outcomes assessed by symptom resolution time, treatment modifications, and BCG discontinuation.

Statistical Analysis

Descriptive statistics were used to summarize patient demographics, symptom prevalence, treatment approaches, and clinical outcomes. Continuous variables were reported as mean where appropriate. Categorical variables were expressed as percentages.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki. Given its retrospective nature and the use of anonymized patient data, formal approval from an institutional ethics committee was not required. Patient confidentiality was strictly maintained throughout the study.

Results

Patient Characteristics

This study included 20 patients with a mean age of 62.2 years (48–80), most over 60. Males comprised 85.0% of the cohort, aligning with bladder cancer's higher prevalence in men. Regarding smoking history, 15.0% were active smokers, 80.0% former smokers, and 5.0% never smoked, highlighting tobacco exposure as a key risk factor. Prior NMIBC was noted in 35.0% of patients, with varying recurrence-free periods. Among them, 65.0% had no previous recurrences, while 35.0% had undergone prior BCG therapy.

Tumor Characteristics

Tumor size was a significant parameter in our cohort, with 80.0% of tumors classified as large (>3 cm) and 20.0% as small (≤3 cm). CIS (carcinoma in situ) was present in some cases, either as an associated finding or as a standalone lesion, but its specific distribution requires further stratification. The predominance of large tumors suggests a population at higher risk for recurrence and progression, warranting aggressive treatment strategies such as BCG therapy.

Post-BCG Complications

All patients (100.0%) experienced complications post-BCG, with varying severity. LUTS were the most common, significantly impacting daily life. Pollakiuria was universal, averaging 6.2 daytime and 7.8 nocturnal voids, with nocturia causing sleep disturbances. Urgenturia affected all patients, leading to distress and reduced quality of life. Dysuria occurred in 65.0%, peaking after instillation but improving with treatment. Hypogastric pain was reported in 60.0%, mostly mild to moderate, responding to symptomatic care. Systemic symptoms were rare; no fevers were observed. Hematuria appeared in 15.0% but was transient, resolving with hydration and monitoring.

Treatment and Symptom Management

Management was primarily supportive, tailored to symptom severity. Fluoroquinolones (Ofloxacin) with corticosteroids were used in 50.0% of cases, while corticosteroids alone were prescribed in 30.0%, reflecting their role in controlling inflammation and discomfort.

Follow-Up Outcomes

Most patients improved within two months. Complete symptom resolution was reported in 55.0% within one month and 25.0% by the second month. However, 15.0% showed no improvement after one month, indicating a prolonged inflammatory response requiring close monitoring. Overall, 80.0% achieved resolution, reinforcing the generally self-limiting nature of BCG-related side effects.

Discussion

Intravesical BCG therapy is the cornerstone of high-risk NMIBC treatment, reducing recurrence and progression by triggering a robust immune response. However, this same mechanism causes adverse effects that can impact quality of life and adherence. This study examines 20 patients with post-BCG complications, focusing on LUTS, pain, hematuria, and treatment responses.

The high prevalence of BCG-related side effects observed in our cohort aligns with prior studies, which report that up to 90% of patients undergoing BCG therapy experience some degree of irritative urinary symptoms [5,6]. In our study, all patients (100.0%) developed pollakiuria and urgency, with a mean of 6.2 daily and 7.8 nocturnal voids. These findings underscore the significant burden BCG-induced bladder inflammation imposes, particularly through nocturnal frequency, which disrupts sleep patterns and diminishes overall well-being. While these symptoms are generally self-limited, they can lead to considerable discomfort and anxiety in affected patients, sometimes prompting premature treatment discontinuation. As such, proper patient education on the expected course of symptoms is crucial to ensuring adherence to the full BCG regimen.

Dysuria, another common side effect, was reported in 65.0% of our cohort, a rate consistent with the literature, which cites dysuria in 50-75% of patients following BCG instillations [7]. The inflammatory response elicited by BCG leads to urothelial

irritation and increased sensory nerve activation, resulting in discomfort during urination [8].

Fever, often considered a hallmark of systemic immune activation following BCG therapy, was notably absent in our cohort. Literature reports estimate the incidence of BCG-induced fever to range between 1-25%, with febrile episodes often reflecting a heightened inflammatory response or, in rare cases, systemic BCG infection [5]. The absence of fever suggests a controlled local immune response without systemic dissemination, likely due to careful patient selection and monitoring.

Hematuria, another frequently encountered side effect, was observed in 15.0% of our patients, a rate within the expected range of 10-30% reported in previous studies [6]. Hematuria following BCG therapy is typically attributed to mucosal irritation and vascular fragility resulting from the immune-mediated response within the bladder. In our cohort, all cases of hematuria were self-limited, requiring no specific interventions beyond increased fluid intake and monitoring.

The findings of this study provide several key insights into the management of BCG-related adverse effects, emphasizing the importance of symptom monitoring, patient counseling, and judicious therapeutic interventions.

1. Pollakiuria and Urgency Are Universal but Transient: Lower Urinary Tract Symptoms (LUTS), including pollakiuria and urgency, were present in all patients, yet 80.0% experienced symptom resolution within 1–2 months. This reinforces existing evidence that BCG-induced bladder inflammation is generally self-limited and should not routinely prompt early discontinuation of therapy.
2. Pain Management and Quality of Life Considerations: Hypogastric pain, reported in 60.0% of cases, underscores the need for proactive symptom management to preserve treatment compliance and quality of life. Current literature suggests that alpha-blockers (e.g., tamsulosin) and nonsteroidal anti-inflammatory drugs (NSAIDs) may alleviate BCG-induced discomfort [7].
3. The Role of Antibiotics in Symptom Management: Ofloxacin and corticosteroids were prescribed in 50.0% of cases, reflecting a frequent clinician preference for mitigating inflammation and irritative symptoms. However, emerging evidence suggests that excessive antibiotic use during BCG therapy may diminish its immunotherapeutic effects, potentially attenuating its antitumor activity [8].
4. Persistent Symptoms in a Subset of Patients: While most patients demonstrated symptom resolution within two months, 15.0% continued to experience persistent LUTS beyond one month. This subset may represent individuals with heightened inflammatory responses, underlying bladder dysfunction, or coexisting conditions influencing symptom duration.

This study has several limitations. The small sample size (20 patients) limits the generalizability of our findings, requiring validation through larger, multi-center studies. The retrospective design introduces a risk of recall bias, particularly for self-reported symptoms such as urgency and dysuria. Additionally, the absence of a standardized symptom severity scale (e.g., IPSS for LUTS, VAS for pain) prevents a more precise assessment of symptom burden and treatment response.

Conclusion

This case series reinforces the high prevalence of BCG-induced irritative urinary symptoms, with urgency, pollakiuria, and dysuria affecting most patients. While these symptoms are typically transient, effective management is essential to maintaining treatment adherence and optimizing patient outcomes. Our findings underscore the importance of a proactive, patient-centered approach to symptom control, balancing symptom relief with the therapeutic benefits of BCG. Future research should focus on refining management strategies to enhance both tolerability and long-term efficacy.

Author Contributions: I, AIT MAHANNA Hamza, take responsibility for the integrity of the entire case report and am designated as the guarantor of the manuscript. All authors have made substantial contributions to the conception and design of the case report, the collection or interpretation of data, as well as to the drafting or critical revision of the manuscript, and have approved the final version for publication.

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