

Subsequent Treatments and Outcomes in Bacillus Calmette-Guerin Unresponsive Patients with High-risk Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ: A Real-World Data Analysis

Background

The recommended first-line treatment for patients with high-risk (HR) non-muscle-invasive bladder cancer (NMIBC) is intravesical Bacillus Calmette-Guerin (BCG).

Despite initial activity, BCG fails in up to 50% of these cases¹, with high-risk of disease progression. Limited evidence has been available to characterize real-world treatment patterns and outcomes.

Methods

Study Design: Retrospective, non-interventional real-world cohort study	Population: Patients with HR-NMIBC CIS receiving ≥ 7 BCG doses who experienced CIS recurrence within 12 months
Data: AQUA Registry EHR data with Komodo claims data	Outcomes Assessed: Subsequent treatment patterns, time to next therapy, and real-world recurrence /progression

Results

From >11,000 patients treated with BCG, ~10% experienced CIS recurrence within 12 months after their last dose.	Median time from recurrence/progression to next treatment was ~3 months, highlighting rapid disease progression (IQR: 41, 346).
Among BCG-unresponsive HR-NMIBC CIS patients:s-ingle-agent intravesical chemotherapy was the most common subsequent therapy (~45%).	Treatment patterns varied substantially across practices, underscoring real-world heterogeneity not visible in trials.

Conclusion

This study demonstrates how AQUA's depth of longitudinal EHR data enables robust real-world evaluation of outcomes that are otherwise poorly captured such as CIS response and post-BCG disease recurrence. AQUA provides a scalable platform to quantify unmet need, benchmark real-world effectiveness, and inform development and positioning of novel bladder-sparing therapies in HR-NMIBC.