E7

Quality of care measures among patients with recurrent, papillary-only bacillus Calmette-Guérin experienced high-risk non-muscle invasive bladder cancer

Ali Raza Khaki[1], Mukul Singhal[2], Bruno Emond[3], Carmine Rossi[3], Rebecca Bungay[4], Steven Liu[5], Dominic Pilon[3], Michael D. Fabrizio[6]

[1]Stanford University School of Medicine, Palo Alto, CA; [2]Johnson & Johnson, Horsham, PA; [3]Analysis Group ULC, Montréal, QC; [4]Analysis Group ULC, Toronto, ON; [5]Analysis Group, Inc., Boston, MA; [6]Medstar Georgetown University Hospital, Washington, DC

Key Takeaway

For Medicare-insured BCG-experienced patients with recurrent, papillary-only HR-NMIBC in the United States, significant gaps in QoC remain

Conclusions

Important gaps in care persist for BCG-experienced patients with recurrent, papillary-only HR-NMIBC, particularly in monitoring, treatment, and healthcare services received

More consistent assessment of QoC measures for patients with HR-NMIBC could help address these gaps in care and improve both short- and long-term patient outcomes

Acknowledgments

This study was sponsored by Johnson & Johnson. The authors would like to thank Shawn Du, Sabree Burbage, and Charmi Patel, employees of Johnson & Johnson for their contributions to the study. The authors would like to thank Zheyi Cao, an employee of Analysis Group, Inc., for her assistance with the data analysis.

Disclosures

A. R. Khaki is an employee of Stanford University School of Medicine and has received grants from Johnson & Johnson, Pfizer, 23andMe, and Acrivon Therapeutics outside of this work. M. Singhal is an employee and stockholder of Johnson & Johnson.B. Emond, C. Rossi, R. Bungay, S. Liu, and D. Pilon are employees of Analysis Group, ULC/Inc., a consulting company that has provided paid consulting services to Johnson & Johnson. M. D. Fabrizio is an employee of MedStar Georgetown University Hospital and has served in a consulting role for Johnson & Johnson, Dendreon, Teleflex Medical, and Specialty Networks, and has served on speaker's bureau for Astellas Pharma, Bayer, Pfizer, and Sumitomo Pharma Oncology.

Background

- High-risk non-muscle invasive bladder cancer (HR-NMIBC) is associated with a high disease burden and substantial likelihood of recurrence and progression, requiring close surveillance and management through multiple interventions[1,2]
- Patients who experience disease recurrence after treatment with Bacillus Calmette-Guérin (BCG) have few effective bladder-sparing treatment options and experience poor long-term clinical outcomes[3-5]
- Due to the high disease burden, the National Comprehensive Cancer Network (NCCN®) and the American Urologic Association (AUA) Quality (AQUA) Registry have developed several quality of care (QoC) measures aimed at improving patient outcomes[6,7]
- However, real-world data evaluating QoC measures among patients with recurrent, papillary-only HR-NMIBC, particularly those who are BCG-experienced, remain limited

Objective

- To characterize QoC measures among Medicare-insured patients in the US with HR-NMIBC with papillary-only carcinoma who were BCG-experienced and had disease recurrence

Methods

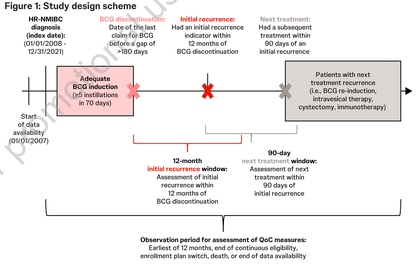
Data source

- SEER-Medicare Data (01/01/2007–12/31/2022) were used, which linked the US National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) cancer registry (containing cases diagnosed since 1973) with the Centers for Medicare & Medicaid Services (CMS) Medicare claims database
- Data were de-identified and complied with the Health Insurance Portability and Accountability Act (HIPAA) regulations

Study design and study population

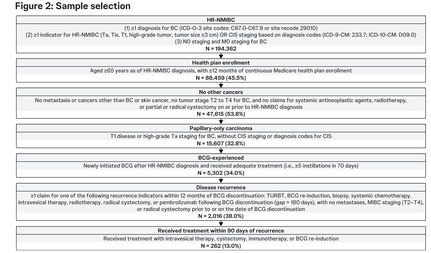
- A retrospective longitudinal study was conducted (**Figure 1**)
- The index date was defined as the date of HR-NMIBC diagnosis
- The baseline period was defined as the 12-month period of continuous enrollment prior to the index date, while the observation period spanned from the index date until the earliest of 12 months, end of continuous enrollment, plan switch, death, or end of data availability (12/31/2022)
- BCG-experienced patients aged ≥65 years with HR-NMIBC with papillary-only carcinoma, who experienced disease recurrence within 12 months of BCG discontinuation and initiated subsequent bladder cancer (BC)-related treatment within 90 days following recurrence were included (**Figure 2**)
  - BCG-experienced with recurrent disease was defined as the discontinuation of BCG treatment (based on a gap >180 days) following adequate induction (i.e., ≥5 instillations in 70 days), with an indicator of disease recurrence (i.e., evidence of transurethral resection of bladder tumor [TURBT], biopsy, intravesical or systemic chemotherapy, radiotherapy, radical cystectomy, pembrolizumab, or BCG re-induction) within 12 months after BCG discontinuation
  - Subsequent BC-related treatment observed within 90 days of a disease recurrence indicator included BCG re-induction, other intravesical therapy, cystectomy, or immunotherapy

Figure 1: Study design scheme



BCG: Bacillus Calmette-Guérin; HR-NMIBC: high-risk non-muscle invasive bladder cancer; QoC: quality of care.

Figure 2: Sample selection



BC: bladder cancer; BCG: Bacillus Calmette-Guérin; CIS: carcinoma in situ; HR-NMIBC: high-risk non-muscle invasive bladder cancer; ICD-9-CM/ICD-10-CM: International Classification of Disease, Ninth/Tenth Revision, Clinical Modification; ICD-O-3: International Classification of Diseases for Oncology, Third Edition; TURBT: transurethral resection of bladder tumor.

Study measures and statistical analysis

- Monitoring-, treatment-, and health services-related QoC measures were assessed during the observation period
- Results were reported descriptively using means, standard deviations, and medians for continuous variables, and frequencies and proportions for categorical variables

Results

Patient characteristics

- Overall, 262 BCG-experienced patients with HR-NMIBC with papillary-only carcinoma who received a subsequent treatment within 90 days of disease recurrence were included (**Figure 2**)
- Among these patients, the mean age was 76 years, 78% were male, and 94% were White (**Table 1**)

Table 1: Baseline patient characteristics

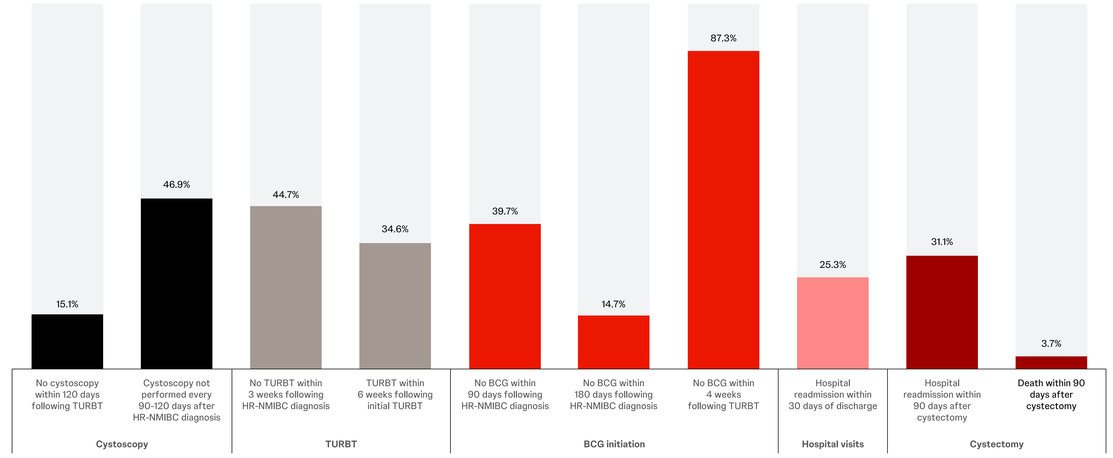
	BCG-experienced patients with recurrent papillary-only HR-NMIBC N = 262
Age at index date, mean ± SD [median]	76.3 ± 6.1 [75.5]
Male sex, n (%)	205 (78.2)
White race, n (%)	245 (93.5)
Index year, n (%)	
2008-2011	29 (11.1)
2012-2015	52 (19.8)
2016-2019	123 (46.9)
2020-2021	58 (22.1)
US region, n (%)	
West	111 (42.4)
South	57 (21.8)
Northeast	48 (18.3)
Midwest	46 (17.6)
Residential setting, n (%)	
Urban	218 (83.2)
Rural	44 (16.8)
Medicare plan enrollment, n (%)	
Fee-for-Service	201 (76.7)
Medicare Advantage	61 (23.3)
Quan-CCI, mean ± SD [median]	1.6 ± 1.8 [1.0]
Urinary tract infection, n (%)	87 (33.2)
Smoking, n (%)	84 (32.1)
Kidney stone, n (%)	35 (13.4)

BCG: Bacillus Calmette-Guérin; CCI: Charlson Comorbidity Index; SD: standard deviation; US: United States.

QoC measures

- Cystoscopy was not routinely performed for 47% of patients and 40% of patients did not initiate BCG within 90 days of HR-NMIBC diagnosis (**Figure 3**)
- A subsequent TURBT within 6 weeks of an initial TURBT was observed among 35% of patients and hospital readmission within 30 days of an initial discharge was observed for 25% of patients
- Hospital readmission or death within 90 days of cystectomy was observed for 31% and 4% of patients, respectively

Figure 3. QoC measures among papillary-only BCG-experienced patients with HR-NMIBC with recurrence



BCG: Bacillus Calmette-Guérin; HR-NMIBC: high-risk non-muscle invasive bladder cancer; QoC: quality of care; TURBT: transurethral resection of bladder tumor.

Limitations

- This study is subject to limitations common to retrospective claims analyses, including potential coding inaccuracies, missing data, and incomplete documentation, which may result in misidentification of study variables
- The HR-NMIBC diagnosis date was defined as the earliest available indicator (i.e., staging or diagnosis codes) in the data, which may not reflect the true disease onset, particularly for cases diagnosed before data availability (i.e., prior to 2008)
- Findings may not be generalizable to patients without Medicare insurance coverage

References

1. Holzbeierlein JM, et al. *J Urol*. 2024;211(4):533–538. 2. Longoni M, et al. *Eur Urol Oncol*. 2025;8(5):1375–1392. 3. Tan WS, et al. *Eur Urol Open Sci*. 2023;53:16–22. 4. Kulkarni GS, et al. *Clin Genitourin Cancer*. 2025;23(3):102313. 5. Li R, et al. *Eur Urol*. 2020;78(3):387–399. 6. Shelton JB, et al. *Urol Pract*. 2021;8(2):209–216. 7. D'Amico TA, et al. *J Natl Compr Canc Netw*. 2020;18(3):250–259.

Urothelial Cancer

Presented at ASCO Genitourinary Cancers Symposium 2026; February 26–28, 2026; San Francisco, CA

This material is distributed for scientific purposes only and not for promotional use