IP35-02

Real-World Outcomes of BCG Retreatment After BCG Failure in Patients with Papillary-Only High-Risk Non-Muscle-Invasive Bladder Cancer: A Retrospective Study in the American Urological Association's Quality Registry

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Key Takeaways

- BCG retreatment is not routinely used and provides limited clinical benefit for patients with papillary-only HR-NMIBC who recurred within 12 months after BCG therapy
- BCG retreatment in patients who recur with HR disease within 12 months is associated with poor outcomes
- Limited benefit with BCG retreatment is observed in both BCG-experienced and BCG-unresponsive patients, supporting prioritization of alternative effective bladder-preserving therapies in patients with papillary-only HR-NMIBC who recur within 12 months after BCG therapy

Conclusions

- Our study showed that immediate BCG retreatment was uncommon (16%), indicating low clinical uptake after initial BCG failure
- BCG retreatment demonstrated limited durability, with high early recurrence rates (over 50% within 1 year) regardless of recurrence timing after the initial BCG therapy
- BCG retreatment outcomes are poor in both BCG-unresponsive and BCG-experienced patients

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Disclosures

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Introduction

- Bladder cancer is among the most common cancers worldwide, with non-muscle-invasive bladder cancer (NMIBC) comprising about 75% of new bladder cancer diagnoses[1]
- High-risk NMIBC (HR-NMIBC) is primarily managed with intravesical Bacillus Calmette-Guérin (BCG) therapy, which significantly reduces recurrence and progression[1,2]
- Despite BCG therapy, approximately 40% of patients experience treatment failure, increasing recurrence risk and progression, and often require further treatment[1,2]
  - In certain cases, BCG retreatment is considered a subsequent treatment for these patients[3]
  - There are currently no FDA-approved novel agents to treat BCG-experienced HR-NMIBC with papillary tumors only

Objective

- **To characterize real-world patterns of BCG retreatment and associated outcomes in patients with papillary-only HR-NMIBC who recurred after BCG therapy**

Methods

Data source and eligibility

- Data collected from the American Urological Association Quality (AQUA) registry for patients diagnosed with NMIBC from 2015-2023; data cutoff: December 2024

Inclusion criteria

- Patients with ≥5 weekly BCG doses and with papillary-only HR-NMIBC (high-grade Ta or any T1) who recurred within 12 months after the last BCG dose
- Patients with at least one year of follow-up after the last BCG dose

Exclusion criteria

- Presence of CIS at the time of recurrence
- Patients with evidence of muscle-invasive bladder cancer (MIBC) or metastasis prior to BCG retreatment

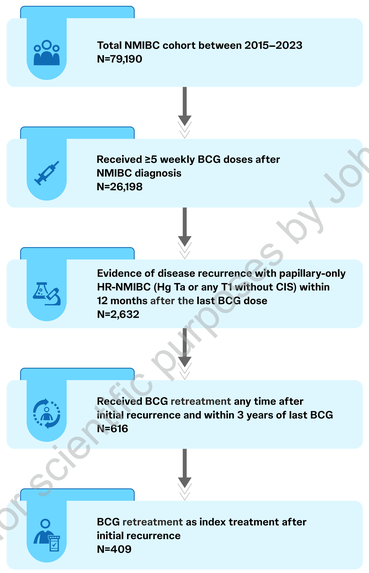
Outcome definitions

- **Disease recurrence:** Evidenced by transurethral resection of bladder tumor (TURBT), biopsy, or subsequent therapy following cystoscopy
- **BCG retreatment:** Reinitiation of adequate BCG induction (≥5 weekly doses) after recurrence and within 3 years of initial BCG
- **Disease-free survival (DFS):** The time from BCG retreatment initiation to first recurrence, progression (≥T2/metastatic disease), or death
  - DFS was reported overall, by timing of recurrence (<6 vs 6–12 months) after initial BCG treatment, and within BCG-experienced vs BCG-unresponsive subgroups
- **BCG-unresponsive:** Patients who meet following criteria: (i) receipt of adequate BCG induction (≥5 weekly BCG doses, with a gap ≤14 days between consecutive doses) and ≥2 maintenance doses (additional weekly doses administered within 6 months of index BCG); and (ii) disease recurrence within 6 months of the last BCG dose
- **BCG-experienced:** Patients who did not meet all criteria for BCG-unresponsive disease

Results

- Of 2,632 patients with papillary-only HR-NMIBC, 24% (616) received BCG retreatment **at any time** following recurrence, including 16% (409) who received BCG retreatment as **subsequent therapy** immediately following recurrence and were further analyzed (**Figure 1**)

Figure 1: Flow diagram of patient selection for the BCG retreatment cohort



BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; Hg, high grade; HR, high-risk; N, total number of patients at each step; NMIBC, non-muscle-invasive bladder cancer.

- Among 409 patients, the median age was 75 years (IQR, 68–81) and the majority were male (82.6%; **Table 1**)
- The median number of prior BCG doses was 6 (**Table 1**)

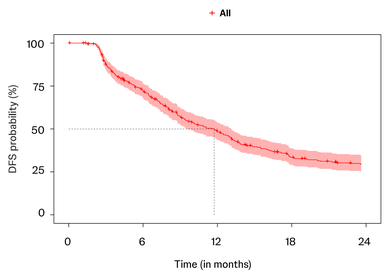
Table 1: Baseline characteristics of BCG retreatment patients by timing of recurrence and BCG subgroups

Baseline characteristics	Total (N=409)	Timing of recurrence		BCG subgroup	
		Recurrence within 6 months (n=230)	Recurrence within 6–12 months (n=179)	BCG-Experienced (n=377)	BCG-Unresponsive (n=32)
Age (at index), mean (SD)	73 (8.36)	73 (8.13)	73 (8.67)	73 (8.44)	77 (6.78)
Age (at index)	75 (68–81)	74 (68.25–80)	76 (68–81)	74 (68–81)	78 (72–82)
Age category					
<65	63 (15.4)	33 (14.3)	30 (16.8)	62 (16.4)	1 (3.1)
65–69	62 (15.2)	36 (15.7)	26 (14.5)	57 (15.1)	5 (15.6)
70–74	78 (19.1)	54 (23.5)	24 (13.4)	72 (19.1)	6 (18.8)
≥75	206 (50.4)	107 (46.5)	99 (55.3)	186 (49.3)	20 (62.5)
Sex					
Male	338 (82.6)	187 (85.0)	151 (84.4)	313 (83.0)	25 (78.1)
Female	71 (17.4)	33 (15.0)	28 (15.6)	64 (17.0)	7 (21.9)
Race[a]					
White	295 (92.5)	174 (94.6)	121 (89.6)	271 (92.2)	24 (96.0)
Black or African American	18 (5.6)	10 (5.4)	8 (5.9)	17 (5.8)	1 (4.0)
Native American and Alaska Native	1 (0.3)	0	1 (0.7)	1 (0.3)	0
Asian or Pacific Islander	2 (0.6)	0	2 (1.5)	2 (0.7)	0
Other	3 (0.9)	0	3 (2.2)	3 (1.0)	0
Ethnicity[b]					
Not Hispanic or Latino	299 (94.9)	174 (96.7)	125 (92.6)	275 (94.5)	24 (100)
Hispanic or Latino	16 (5.1)	6 (3.3)	10 (7.4)	16 (5.5)	0
Follow-up, months	28.34 (14.68–48.36)	28.34 (15.46–49.04)	28.37 (13.97–47.11)	28.77 (14.40–49.53)	22.39 (15.42–40.77)
Tumor stage (at index)[c]					
T1	278 (68.0)	158 (68.7)	120 (67.0)	258 (68.4)	20 (62.5)
Hg Ta	131 (32.0)	72 (31.3)	59 (33.0)	119 (31.6)	12 (37.5)
BCG doses received prior to recurrence	6 (5–21)	6 (5–21)	6 (5–21)	6 (5–21)	9.5 (8–18)
5–6	309 (75.6)	171 (74.3)	138 (77.1)	309 (82.0)	0
≥7	100 (24.4)	59 (25.7)	41 (22.9)	68 (18.0)	32 (100)

Data presented as n (%) or median (IQR), unless noted otherwise. Data reported at index indicate baseline assessment of variables.
[a]Calculated out of 319 patients with known race information. [b]Calculated out of 315 patients with known ethnicity information. [c]Tumor stage within 90 days before or 30 days after index date.
BCG, Bacillus Calmette-Guérin; Hg, high grade; IQR, interquartile range; N, total number of patients analyzed; n, number of patients at each variable/subgroup; SD, standard deviation.

- The median disease-free survival (mDFS) was 11.74 months (95% CI, 9.53–13.12; **Figure 2**)
- 71% of patients experienced recurrence or progression within 24 months (**Figure 2**)

Figure 2: DFS in patients receiving immediate subsequent BCG retreatment



Time (in months)	0 m	6 m	12 m	18 m	24 m
N at Risk	409	279	178	114	92
DFS Probability	100%	72%	49%	34%	29%

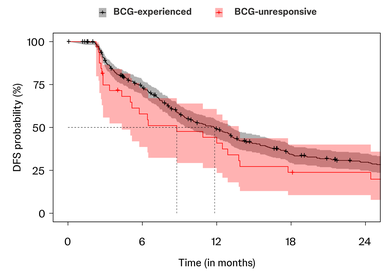
N	Events	Median (months)	0.95 LCL	0.95 UCL
409	302	11.74	9.53	13.12

BCG, Bacillus Calmette-Guérin; DFS, disease-free survival; LCL, lower confidence limit; m, month; N, total number of patients; UCL, upper confidence limit.

- Analysis of DFS by timing of recurrence after the initial BCG therapy showed suboptimal outcomes for patients who received BCG retreatment
  - mDFS was 10.03 months (95% CI, 8.68–12.46) in patients with recurrence within 6 months
  - mDFS was 13.15 months (95% CI, 11.11–17.59) in patients with recurrence within 6–12 months

- The mDFS (95% CI) following BCG retreatment was 11.84 months (9.60–13.18) in BCG-experienced patients and 8.78 months (4.34–13.78) in BCG-unresponsive patients (**Figure 3**)

Figure 3: DFS by BCG subgroup (experienced vs unresponsive)



BCG-Experienced[a]

Time (in months)	0 m	6 m	12 m	18 m	24 m
N at Risk	377	262	165	107	86
DFS Probability	100%	73%	49%	34%	30%

N	Events	Median Survival Time (months)	Confidence Interval
377	276	11.84	9.6–13.18

BCG-Unresponsive[b]

Time (in months)	0 m	6 m	12 m	18 m	24 m
N at Risk	32	17	13	7	6
DFS Probability	100%	58%	44%	24%	24%

N	Events	Median Survival Time (months)	Confidence Interval
32	26	8.78	4.34–13.78

[a]Patients who did not meet all criteria for BCG-unresponsive disease were classified as BCG-experienced. [b]Patients were classified as BCG-unresponsive if all of the following criteria were met: (i) receipt of adequate BCG induction (≥5 weekly BCG doses, with a gap ≤14 days between consecutive doses) and ≥2 maintenance doses (additional weekly doses administered within 6 months of index BCG); and (ii) disease recurrence within 6 months of the last BCG dose.
BCG, Bacillus Calmette-Guérin; DFS, disease-free survival; m, month; N, total number of patients.

Limitations

- The electronic medical record database, linked with healthcare claims, does not capture detailed clinical information, including test results and reasoning for procedures such as TURBT and biopsy, which may limit our ability to accurately interpret and confirm potential recurrence events
- The AQUA Registry primarily collects data from community urologists and other urologic care providers. Therefore, information on patient's non-urological medical care (eg, non-cancer-related comorbidities managed outside of specific institutions) may be incomplete or unavailable
- The interpretation of outcomes in the BCG-unresponsive cohort is limited by the small sample size
- Participation in the AQUA Registry is voluntary and may not fully reflect the diversity of urologic practice across the US, potentially limiting the generalizability of results to populations beyond those represented in the registry

References

1. Kodera A, et al. *Cureus* 2023;26;15(6):e40962. **2.** Maroof H, et al. *Cancer Pathog Ther* 2023;2(2):74–80. **3.** Holzbeierlein JM, et al. *J Urol* 2024;211(4):533–538.

Urothelial Cancer

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