

A Real-World US Community-Based Evaluation of Recurrence Among Intermediate-Risk Non-Muscle-Invasive Bladder Cancer Patients Treated With Bacillus Calmette-Guérin

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Introduction

- Bladder cancer is the seventh most commonly diagnosed cancer in the United States (US), with approximately 75% of patients having non-muscle-invasive bladder cancer (NMIBC) at diagnosis.^{1,2} NMIBC risk categories include low-risk, intermediate-risk (IR), and high-risk. Recurrence and progression rates remain poorly characterized for IR NMIBC.
- The current standard of care for patients with IR NMIBC is transurethral resection of the bladder tumor (TURBT) followed by intravesical therapy, including induction therapy with Bacillus Calmette-Guérin (BCG)³

Objective

- This study aimed to evaluate real-world clinical outcomes of BCG-naïve IR NMIBC patients after BCG induction initiation

Methods

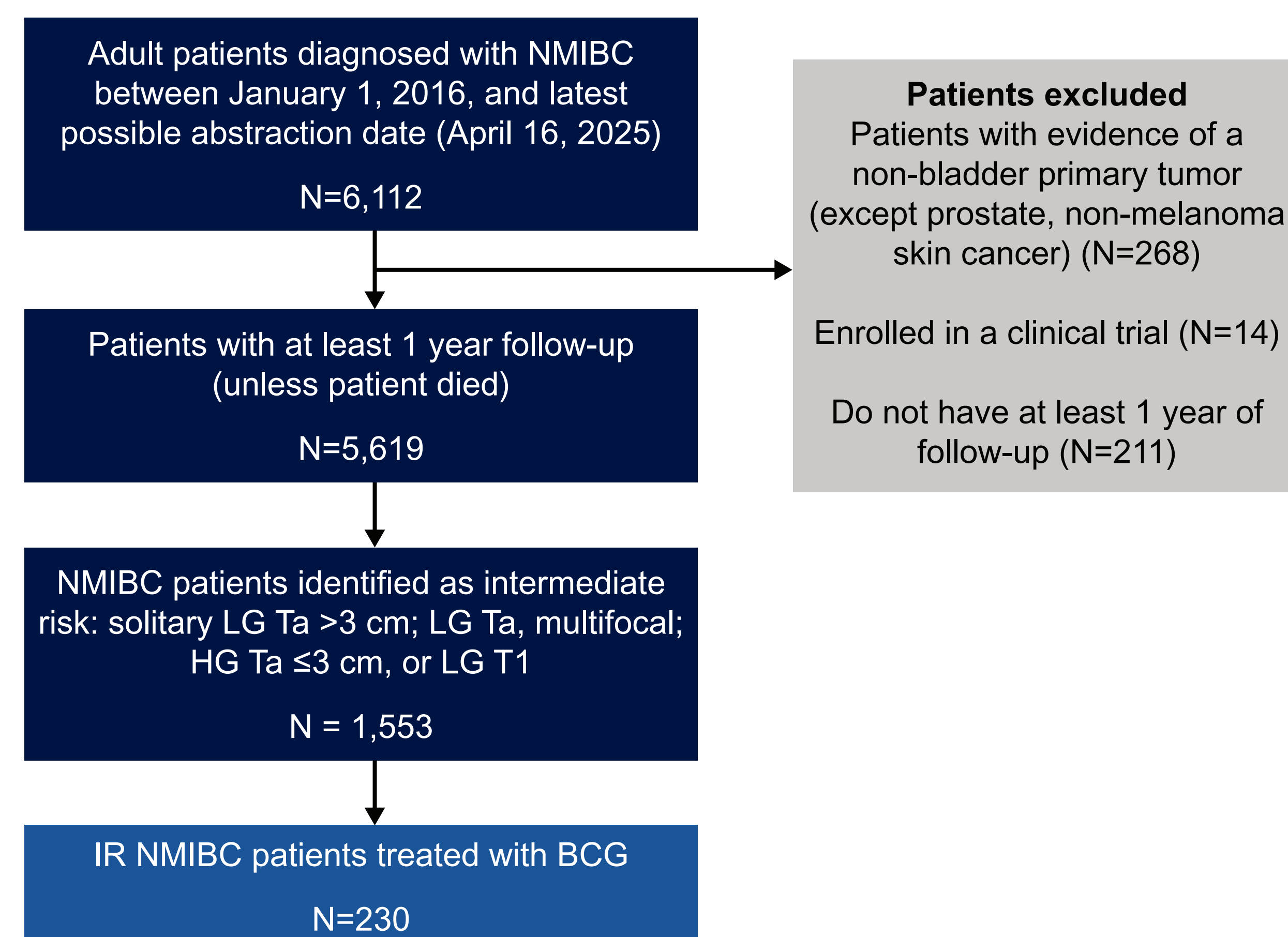
Study design: Retrospective cohort study.

Data source: Data were identified from N-Power Medicine's Real-World Bladder Analytical Dataset, a longitudinal dataset integrating health care information from cancer registries, electronic medical records, laboratory reports, and external sources, enriched with manual abstraction by certified Oncology Data Specialists (ODS). The network includes over 1000 oncologists from four, not-for-profit, community health systems in the U.S.

Study identification period: January 1, 2016, to April 16, 2025.

Study population: The population included adult patients diagnosed with IR NMIBC based on AUA/SUO 2024 amendment criteria (solitary LG Ta >3 cm; LG Ta, multifocal; HG Ta ≤3 cm, or LG T1) who were BCG-naïve and then went on to receive BCG therapy⁴ (Figure 1).

Figure 1. Patient attrition flow chart



BCG, Bacillus Calmette-Guérin; IR, intermediate-risk; NMIBC, non-muscle-invasive bladder cancer.

Data cutoff: 16 April 2025.

Statistical analysis: Patient and clinical characteristics were assessed descriptively. Any disease recurrence and progression (muscle-invasive bladder cancer [MIBC], distant metastasis) after the index date (BCG initiation date) was identified. Recurrence-free survival (RFS; time from the index date to first disease recurrence or death from any cause, whichever occurred first) was estimated using Kaplan-Meier analyses among all eligible patients and in the age 65+ subgroup. Patients were censored at earliest date of another cancer diagnosis or last abstraction, whichever occurred first. Percentage of patients who had a TURBT more than once (re-TURBT) is reported.

Results

Patient characteristics (Table 1)

- A total of 230 BCG-naïve IR NMIBC patients (n=181 65+ years) were included (median age 71 years, 76% male, 92% White, 65% Medicare insurance [81% 65+ years])
- Seventeen percent of the patients were diagnosed with either solitary LG Ta >3 cm or LG Ta and multifocal; 69% HG Ta ≤3 cm, and 13% LG T1 at IR NMIBC diagnosis
- Median time from IR NMIBC diagnosis to BCG induction initiation was 7 weeks

Table 1. Baseline characteristics for BCG-treated IR NMIBC patients

Characteristic	Overall, N=230
Age at initial diagnosis, n	
Median (IQR)	71 (65, 79)
Sex, n (%)	
Male	175 (76%)
Race, n (%)*	
White	211 (92%)
Black/African American	13 (5.7%)
Asian	3 (1.3%)
Other	3 (1.3%)
Unknown	3
Smoking history at initial diagnosis, n (%)*	
Current/former	159 (70%)
Never	67 (30%)
Unknown	10
Staging, n (%)	
Low-grade T1	31 (13%)
High-grade Ta ≤3 cm	158 (69%)
Low-grade Ta, multifocal	24 (10%)
Low-grade Ta >3 cm, solitary	17 (7%)
Histology, n (%)	
Urothelial	230 (100%)
Grade at initial diagnosis, n (%)	
High grade	158 (69%)
Low grade	72 (31%)
Charlson Comorbidity Index, n (%)*	
0	90 (52%)
1	25 (14%)
2	22 (13%)
>2	37 (21%)
Unknown	56

*Percentages are based on the number of people for whom data were available. IQR, interquartile range.

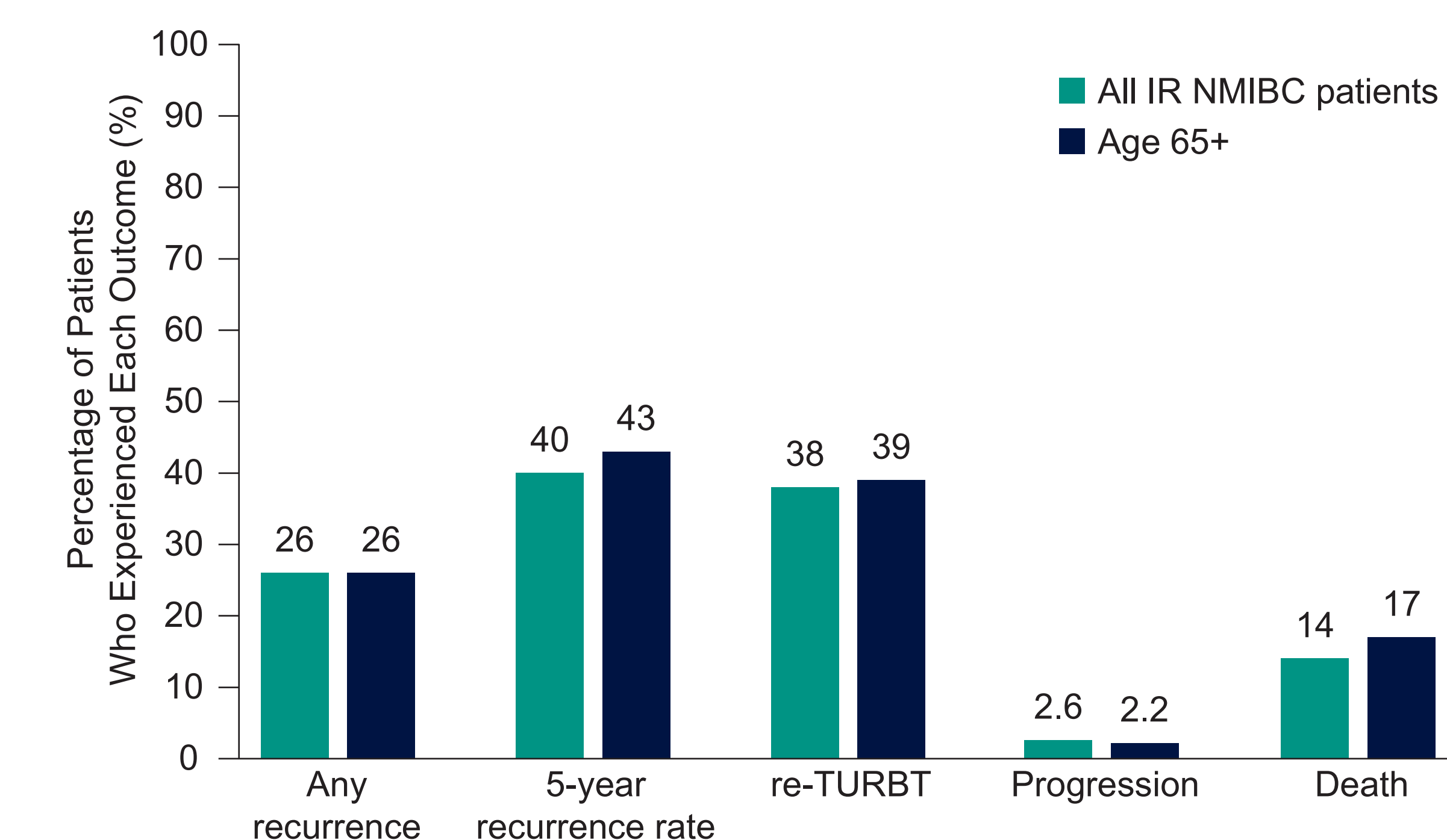
Disease recurrence and progression

During a median follow-up from index date of 38 (min, max [5, 82]) months:

- 26% (60/230) of patients experienced any recurrence at any time (Figure 2)
- 5-year recurrence/death rate was 40%
- 2.6% (6/230) had MIBC and/or distant metastasis
- 38% (88/230) received re-TURBT
- 14% (32/230) of patients died

Similar results were observed for disease recurrence, progression, and deaths in the age 65+ population.

Figure 2. Disease recurrence, progression, and re-TURBT outcomes in BCG-treated IR NMIBC patients

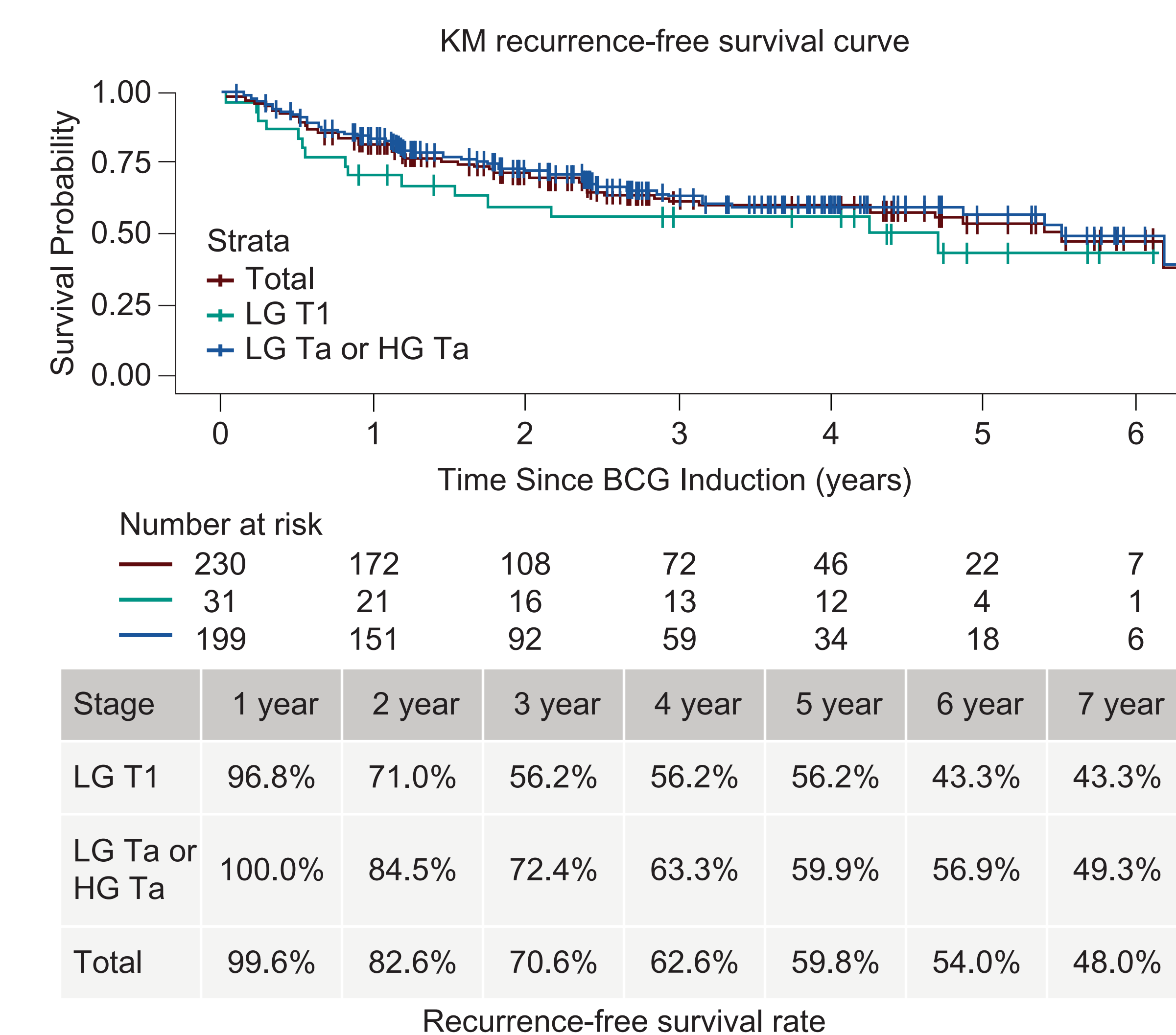


BCG, Bacillus Calmette-Guérin; IR, intermediate-risk; MIBC, muscle-invasive bladder cancer; NMIBC, non-muscle-invasive bladder cancer.

Recurrence-free survival

Median RFS was 5.5 years (95% CI: 4.7-NR) in the total population (Figure 3) and 5.4 years (95% CI: 3.2-NR) in those aged 65+ years (Figure 4). Median time to recurrence or death is shown (Table 2). The RFS at 3 years was 71% with LG T1 slightly and consistently lower than Ta combined groups across all years for the overall population.

Figure 3. KM recurrence-free survival curve for BCG-treated intermediate-risk NMIBC patients (all ages)



BCG, Bacillus Calmette-Guérin; HG, high-grade; KM, Kaplan-Meier; LG, low-grade.

Disclosures

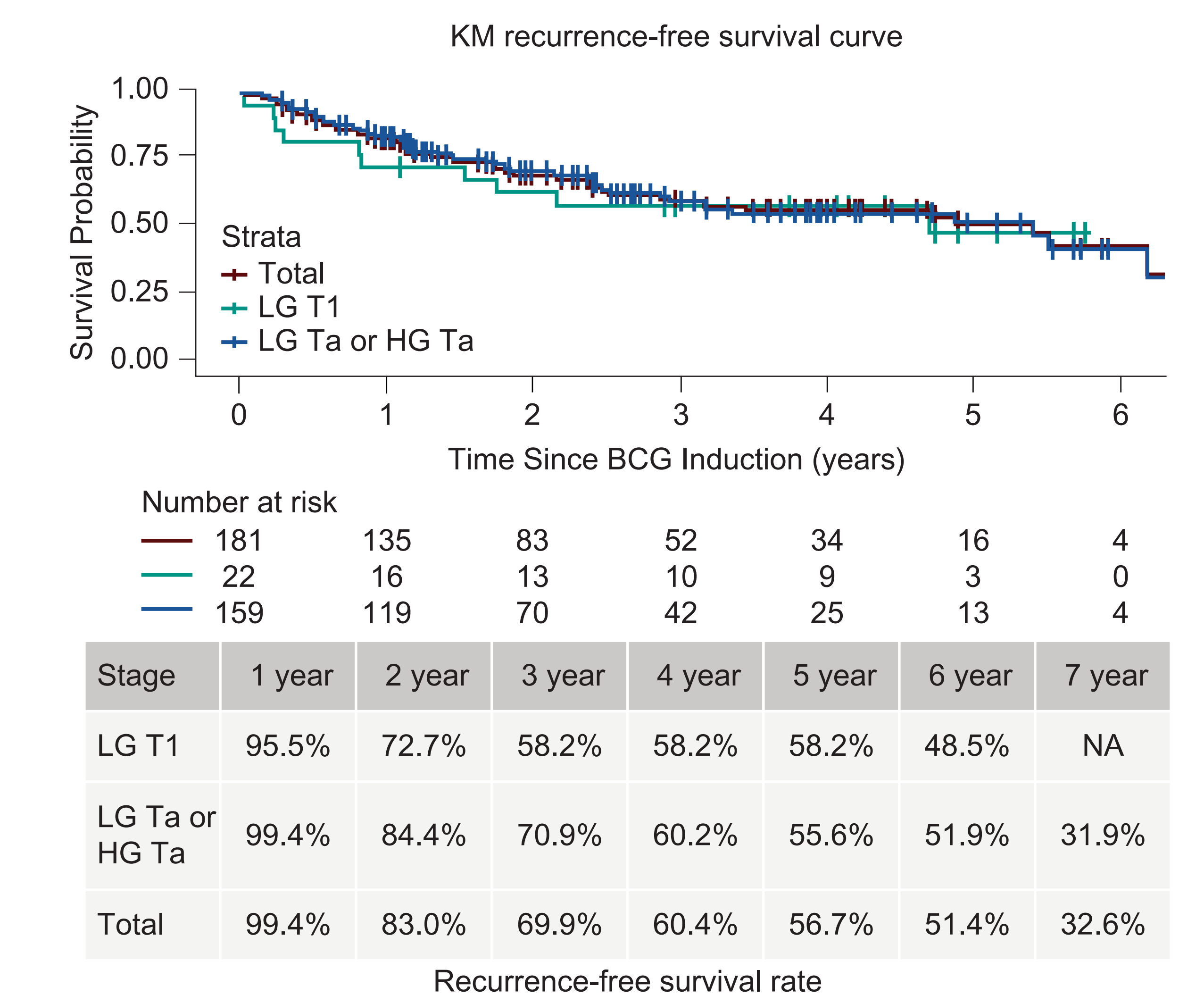
AB, KM, HD, VT, and HL are employees of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, and hold stock of Merck & Co., Inc., Rahway, NJ, USA.

Table 2. Median time to recurrence or death, overall population

Stage	Median time to recurrence or death (years)	95% CI (years)
Total	5.5	4.7-NR
LG T1	4.7	1.5-NR
LG Ta or HG Ta	5.5	4.9-NR

CI, confidence interval; LG, low-grade; HG, high-grade; NR, not reached.

Figure 4. KM recurrence-free survival curve for BCG-treated intermediate-risk NMIBC patients (65+ years)



BCG, Bacillus Calmette-Guérin; KM, Kaplan-Meier.

Limitations

Inability to identify IR NMIBC patients whose classification was based on recurrence within 1 year with LG Ta, as the data did not contain grade at time of recurrence.

Conclusions

BCG-treated patients with IR NMIBC have substantial clinical burden, with approximately 40% experiencing disease recurrence or death from any cause at 5 years post-initial treatment. These findings demonstrate the need for more effective treatments that can reduce both recurrence and disease progression.

References

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