Treatment Pattern, Mortality and Costs Among German BCG-Treated Non-Muscle Invasive Bladder Cancer (NMIBC) Patients

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Quignot N[1], Doobaree U[2], Jiang H[1], Lehmann J[3], **Ghatnekar O[4]**

[1]Certara, Paris, 75, France, [2]Certara - Evidence & Access, London, LON, UK, [3]Klinik für Urologie, Kiel,Germany, [4]Ferring International PharmaScience Center, Copenhagen, Denmark

BACKGROUND

- Intravesical Bacillus Calmette-Guerin (BCG) is the first line treatment for patients with high-risk NMIBC.
- There is a lack of contemporary data on its use in clinical practice and next line treatments in Germany.

OBJECTIVES

- To describe the treatment patterns of adult patients treated with BCG as well as their health resource utilisation, cost burden and mortality rate.

METHODS

Study design and data source

- Retrospective cohort study using data from a representative subset (7% coverage) of the German statutory health insurance (*Gesetzliche Krankenversicherung).*

Study population

- Bladder cancer patients (ICD-10 code: C67* or D09.0) who initiated BCG treatment between 01/01/2012 and 31/12/2017*. Other inclusion/exclusion criteria are shown in Figure 1.
- The index date was the date of dispensing of the first BCG instillation for each patient;
- Patients were followed up from the index date until 31/12/2019.

Definition of progression

- Muscle Invasive Bladder Cancer (MIBC) evidence was defined as radiotherapy, systemic antineoplastic agent, metastasis diagnosis or procedure, death within 6 months of last BCG.

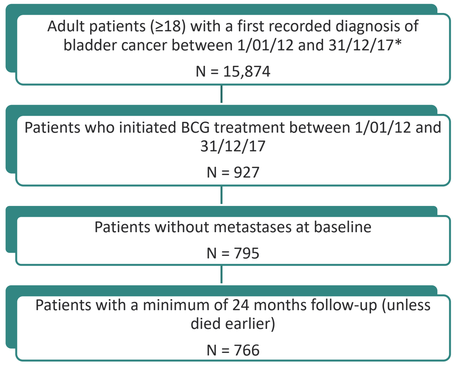
*Update analysis – Initial analysis included patients up to 2016.

RESULTS

Patient characteristics

- A total of 766 patients were included (Figure 1).

Figure 1. Patient selection chart



*Patients with a relevant recorded diagnosis only may not be all true bladder cancer cases (due to possible miscoding or temporary coding while diagnoses were being confirmed) so the attrition rate between step 1 and step 2 should be regarded carefully

- Selected patient characteristics and treatment history are presented in Table 1.

Table 1. Patient baseline characteristics

Patient characteristics	BCG-treated bladder cancer patients N = 766
Gender: male N (%)	658 (86%)
Age at BCG initiation Mean (SD), years	71.0 (9.8)
Time from first recorded diagnosis of bladder cancer to BCG initiation Mean (SD), months	6.9 (7.9)
Charlson Comorbidity Index Mean (SD)	4.5 (2.7)
Number of transurethral resection of bladder tumor (TURBT) Mean (SD)	2.2 (1.1)

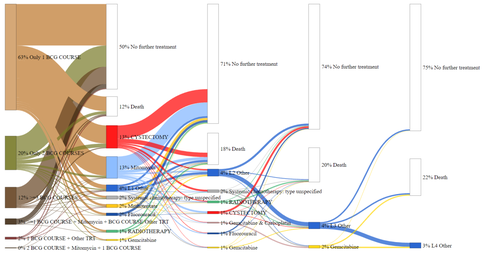
- Mean follow-up (FU) time from BCG initiation was 4.4 (1.7) years.

RESULTS *(cont.)*

Treatment pattern

- Patients received a mean of 13.0 (7.3) BCG instillations during a mean of 13.9 (13.8) months. 36% of patients received TURBT while having BCG therapy; 46% had a TURBT after their last BCG.
- Mean FU after last BCG was 3.3 years, and 480 (63%) patients did not receive any further treatment (including 404 [53%] without any evidence of progression). The other 286 patients experienced at some point (multiple treatments possible):
  - 88 (11%) patients had a systemic antineoplastic agent and/or radiotherapy without cystectomy – *to note, 257 (33%) patients overall had any evidence of progression;*
  - 117 (15%, rate: 24 per 100 patient-year from last BCG) had a cystectomy;
  - 102 (13%) patients received mitomycin (mostly intravesical) *– to note, 98 (13%) patients received intravesical instillation of another agent at any point after BCG.*

Figure 2. Treatment pattern of BCG-treated patients



Note: treatment categories with frequency <5 patients were merged as 'other'

Mortality

- 24% of patients died during FU; the 3-year overall survival rate was 87% from BCG initiation. 3-year survival rate was 95% for patients w/o further treatment nor MIBC evidence after BCG, 88% for patients who received intravesical instillation of another agent at any point after BCG, 73% for patients with MIBC evidence.

RESULTS *(cont.)*

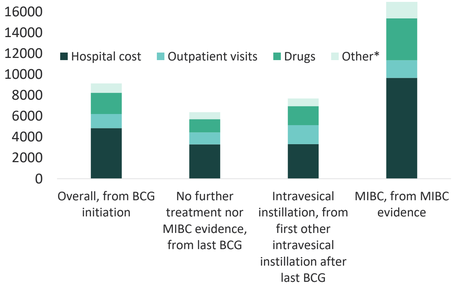
Healthcare resource use and costs

- After BCG initiation, 93% of patients in the overall cohort had at least one hospital stay. The rate of was 145 hospital admissions per 100 person-year and median length of stay (LoS) was 5.0 days.
- Hospital admission rate after BCG was higher for patients with evidence of progression than for those treated with another intravesical agent.
- Mean (SD) hospital cumulative LoS in the 3 months after cystectomy was 30.5 (19.1) days.

Costs

- For the overall cohort, after BCG initiation, total cost (including hospitalizations, primary care, drugs dispensed and other benefits and sick leaves) was €9,127 per patient-year (Figure 3).
- For patients without further selected treatment after BCG nor MIBC evidence or patients with other intravesical instillation, total cost was €6,379 and €7,683 per patient-year, respectively (Figure 3).
- Total cost for patients with evidence of MIBC was €16,933 per patient-year, from MIBC evidence (Figure 3).

Figure 3. Costs per patient-year, overall and in patient subgroups



LIMITATIONS

- Similar to other claims database studies, miscoding and delays in coding may have introduced biases in this study
- Staging, morphology and grading data were unavailable in this data source.
- Costs include costs reimbursed by the health insurance; other indirect costs were not included and the overall economic burden of the disease may be higher than estimated in our study.

CONCLUSIONS

- After last BCG instillation
  - ➢ 53% patients did not receive any further treatment nor presented MIBC evidence, indicating that they may not have had recurring or progressing disease during the FU available for this study
  - ➢ 13% patients received intravesical instillation of another agent, indicating that they may have had recurring disease
  - ➢ 33% patients had evidence of progression
  - ➢ 15% patients had a cystectomy
- The cost burden following BCG treatment is high, with per-patient mean costs ranging from €6,379 to €16,933, depending on type of treatments (including no treatment) NMIBC patients received and whether they progressed to MIBC.
- Timely and effective treatment may reduce the morbidity, mortality and resource use/costs among NMIBC patients.

DISCLOSURES

This study is funded by Ferring, and conducted independently by Certara. JL received consulting fees from Ferring. NQ, UD and HJ are full-time employees of Certara and received consulting fees from Ferring to conduct the study. OG is full-time employee at Ferring

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