Development of an algorithm estimating cisplatin-based chemotherapy eligibility among patients with muscle-invasive bladder cancer using real-world data

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Abstract

Cisplatin-based neoadjuvant chemotherapy is recommended for muscle-invasive bladder cancer (MIBC). Galsky criteria are commonly used to assess if patients are fit to receive cisplatin. This study used Optum's de-identified Market Clarity Data to approximate Galsky criteria among patients with MIBC. Patients who met ≥ 1 of the criteria were considered not eligible for cisplatin (CIS-I).

Of the 2210 patients with MIBC included in this study, 1184 (53.6%) were CIS-I by the proxy criteria, consistent with established clinical estimates of ~50% eligibility. Ineligible patients were older (mean [SD] 73.5 [9.9] vs 66.8 [10.9] years), more likely to have Medicare (69.9% vs 49.2%), had higher baseline Charlson comorbidity scores (mean [SD] 2.1 [1.8] vs 1.0 [1.3]) and poorer overall survival (median 57 months vs not reached). As treatment options for MIBC continue to evolve, using proxy criteria to estimate treatment eligibility may support future research using real-world data.

Introduction

- MIBC represents approximately 25% of bladder cancer in the US[1]
- Cisplatin-based neoadjuvant chemotherapy with/without perioperative immunotherapy is a recommended treatment for MIBC,[1] but up to 52% of patients are ineligible for cisplatin (CIS-I)[2]
- Eligibility criteria, standardized by Galsky et al,[3] require clinical assessment of patients for whom data are often unavailable in real-world analyses
- This study used real-world data to develop a cisplatin eligibility algorithm that approximates Galsky criteria in patients with MIBC in the US to determine cisplatin ineligibility

Methods

Patient Identification

- Patients diagnosed with MIBC between Jul 2016 and Sep 2023 were identified using Market Clarity, which contains claims and electronic health records (EHRs)
- The index date was the earliest date of diagnosis
- Additional eligibility criteria included age ≥ 18 years and continuous insurance enrollment (CE) for ≥ 6 months of baseline and ≥ 3 months of follow-up
- Follow-up lasted until death, loss of CE, or Dec 2023
- Exclusion criteria were metastases or other primary cancer in baseline, use of Bacillus Calmette-Guérin (BCG) in follow-up, or pregnancy or clinical trial participation in baseline or follow-up

Table 1. Galsky and proxy criteria for cisplatin ineligibility

Original Galsky Criteria	Market Clarity Proxy Criteria[a]
ECOG performance score ≥ 2	ECOG performance score ≥ 2[b]
Creatinine clearance < 60 mL/min	Diagnosis of renal failure[c]
CTCAE v4 grade ≥ 2 audiometric hearing loss	Diagnosis of, procedures, or equipment related to hearing loss[c]
CTCAE v4 grade ≥ 2 peripheral neuropathy	Diagnosis of peripheral neuropathy[c]
NYHA Class III heart failure	Diagnosis of heart failure[c]

[a]The presence of ≥ 1 criteria defined cisplatin ineligibility based on administrative claims and EHRs; [b]from EHRs; [c]from medical claims. Abbreviations: CTCAE v4, Common Terminology Criteria for Adverse Event, version 4; ECOG, Eastern Cooperative Oncology Group; EHR, electronic health record; NYHA, New York Heart Association.

Outcomes and Statistical Methods

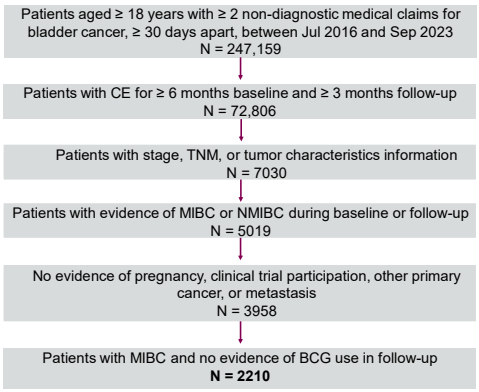
- Patients were classified as CIS-I if they met ≥ 1 criteria used to approximate Galsky[3] (Table 1)
- Proxy criteria were primarily based on administrative claims; EHR data were also used
- Cisplatin eligibility status was assessed from baseline through the earliest date of chemotherapy, radiation therapy, surgery, or the end of the observation period
- Patient characteristics by cisplatin eligibility status (CIS-I vs cisplatin-eligible, CIS-E) were compared
- Kaplan-Meier methods and log-rank statistics were used to examine overall survival (OS)

Results

Study Population

- 2210 patients with MIBC were identified (Fig. 1)
- Of these, 1184 were ineligible for cisplatin (53.6%)

Figure 1. Patient selection and attrition



Abbreviations: BCG, Bacillus Calmette-Guérin; CE, continuous enrollment; MIBC, muscle-invasive bladder cancer; NMIBC, non-muscle invasive bladder cancer; TNM, tumor-node-metastasis

Cisplatin Ineligibility by Proxy Criteria (Table 2)

- Diagnosis of renal failure eliminated the most patients from eligibility (n = 727, 32.9% of all patients)
- The only EHR-based criterion (ECOG) eliminated the fewest patients (n = 179, 8.1%)

Table 2. Patients determined ineligible for cisplatin by proxy criteria

Proxy Criteria[a]	Ineligible Patients[b], n (%)
ECOG performance score ≥ 2[c]	179 (8.1%)
Renal failure diagnosis[d]	727 (32.9%)
Hearing loss diagnosis, procedures, or equipment[d]	255 (11.5%)
Peripheral neuropathy diagnosis[d]	327 (14.8%)
Heart failure diagnosis[d]	433 (19.6%)

[a]The presence of ≥ 1 criteria defined cisplatin ineligibility based on administrative claims and EHRs; [b]patients could meet ≥ 1 ineligibility criteria; [c]from EHRs; [d]from medical claims. Abbreviation: ECOG, Eastern Cooperative Oncology Group; EHR, electronic health record.

Patient Characteristics: CIS-I vs CIS-E (Table 3)

- CIS-I patients were older, more likely to be non-Hispanic Black, and had higher baseline Charlson comorbidity index (CCI) scores, compared with CIS-E, consistent with clinical expectations

Table 3. Baseline demographic and clinical characteristics, by cisplatin eligibility

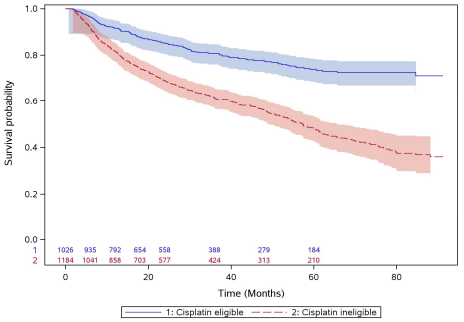
Characteristic	Cisplatin-Eligible (n = 1026)	Cisplatin-Ineligible[a] (n = 1184)	*p*-value
Age, years, mean (SD)	66.8 (10.9)	73.5 (9.9)	**< 0.001**
Female, n (%)	300 (29.2%)	332 (28.0%)	0.534
Race/Ethnicity, n (%)			**0.038**
Non-Hispanic Asian	13 (1.3%)	12 (1.0%)	
Non-Hispanic Black	53 (5.2%)	100 (8.5%)	
Non-Hispanic White	896 (87.3%)	1010 (85.3%)	
Hispanic	26 (2.5%)	24 (2.0%)	
Other/Unknown	38 (3.7%)	38 (3.2%)	
CCI score, mean (SD)	1.0 (1.3)	2.1 (1.8)	**< 0.001**
CCI score category, n (%)			**< 0.001**
0	549 (53.5%)	294 (24.8%)	
1-2	354 (34.5%)	467 (39.4%)	
3-4	105 (10.2%)	290 (24.5%)	
5+	18 (1.8%)	133 (11.2%)	

[a]The presence of ≥ 1 criteria defined cisplatin ineligibility based on administrative claims and EHRs. Abbreviations: CCI, Charlson comorbidity index.

Overall Survival by Cisplatin Eligibility (Fig. 2)

- Kaplan-Meier analysis showed that median OS was shorter among patients with CIS-I (57 months vs not reached for CIS-E), consistent with clinical expectations

Figure 2. Overall survival (95% CI), by cisplatin eligibility



Conclusions

- A proxy algorithm based on real-world data determined that 53.6% of patients with MIBC were ineligible for cisplatin
- This aligns closely with prior estimates based on clinical criteria[2] (52%), supporting the potential of a claims-based approach to estimating eligibility
- CIS-I was driven by claims-based criteria; the only EHR-based component identified a minority of CIS-I
- CIS-I patients were on average older, had greater comorbidity burden, and lower OS during follow-up
- Research implications: the pre-defined algorithm, which attempts to mirror established eligibility criteria, may be useful in cases where there is insufficient clinical information available
- External validation of the algorithm using medical chart review could strengthen the algorithm for use in other claims data

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