Clinical Characteristics and Treatment Patterns on Cisplatin-Eligible vs Cisplatin-Ineligible Muscle-Invasive Bladder Cancer Patients With Intent for Resection: A Multi-Country Retrospective Chart Review in Europe

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Introduction

- Bladder cancer (BC) is the 9th most commonly diagnosed cancer worldwide, with an estimated 614,298 new cases and 220,596 deaths annually. Europe has the highest age-standardized incidence (~12.0 per 100,000 person-years)[1]
- Muscle-invasive bladder cancer (MIBC) represents ~25% of new BC diagnoses. The standard of care is neoadjuvant cisplatin-based chemotherapy followed by radical cystectomy (RC) with pelvic lymph node dissection; however, ~50% of MIBC patients are ineligible for cisplatin[2,3]
- Cisplatin ineligibility is commonly defined by the Galsky criteria: impaired renal function defined as creatinine clearance <60 mL/min, Eastern Cooperative Oncology Group performance status (ECOG PS) ≥2, New York Heart Association (NYHA) class III+ heart failure, or grade ≥2 peripheral neuropathy or audiometric hearing loss[4]
- Despite this consensus definition, real-world clinical characteristics, comorbidities, and treatment patterns of patients with MIBC stratified by Galsky status remain poorly characterized in Europe

Objective

- To describe and compare demographics, clinical characteristics, comorbidities, and treatment patterns of cisplatin-eligible (cis-E) vs cisplatin-ineligible (cis-IE) patients with MIBC planned for RC in routine European practice

Methods

Study design

- A retrospective physician panel-based chart review was conducted in France, Germany, and the United Kingdom (UK) using a standardized electronic case report form. Adult patients (≥18 years old) with investigator-assessed MIBC who planned for an RC between Jan. 1, 2010 and Nov. 1, 2023, and ≥1 healthcare encounter ≥12 months after the index date (unless death occurred during follow-up) were included
- The index date was defined as the date of the planned RC. The baseline period spanned from the date of first MIBC diagnosis to the index date. The observation period extended from the index date to the earliest of death, last clinical visit, or date of chart abstraction (between January 2025 and February 2025)
- Eligible physicians were practicing urologists and medical oncologists recruited from an established network. Each physician abstracted 1-5 randomly selected eligible patient charts
- Cisplatin eligibility was classified per Galsky criteria.[4] Patients meeting ≥1 criterion (creatinine clearance <60 mL/min, ECOG PS ≥2, NYHA class III+ heart failure, grade ≥2 audiometric hearing loss, or grade ≥2 peripheral neuropathy) were classified as cis-IE; all others were classified as cis-E

Study outcomes

- Demographic characteristics were assessed at the index date, or the closest available date, and included age at planned RC, sex, country of residence, smoking status, and body mass index (BMI)
- Clinical characteristics were assessed at the date of MIBC diagnosis, or the closest available date during the baseline period, and included time from MIBC diagnosis to planned RC, year of planned RC, investigator-assessed clinical TNM stage, and ECOG PS
- Comorbidity burden during the baseline period was described using individual conditions, including cardiovascular, metabolic, pulmonary, renal, neurologic, thromboembolic, psychiatric disorders, and prior malignancy history
- Receipt of RC was described, including the primary documented reason when surgery was not performed as planned
- Neoadjuvant and adjuvant therapy patterns were evaluated, including receipt, type, and specific regimens administered

Statistical analysis

- All analyses were stratified by cisplatin eligibility status (cis-E vs cis-IE)
- Demographic and clinical characteristics were summarized descriptively. Continuous variables were reported as means with standard deviations (SD) or medians with ranges, as appropriate, while categorical variables were summarized using frequencies and percentages
- Comparisons of baseline characteristics between cis-E and cis-IE groups were performed using Chi-square tests for categorical variables and two-sample *t* tests for continuous variables. All statistical tests were two-sided, with a significance threshold of *P*<0.05. Unknown data were reported explicitly, and no imputation was performed

Results

- In total, 250 physicians participated and abstracted patient charts. Most were based in Germany (46.4%), followed by France (29.2%) and the UK (24.4%), and were nearly evenly split between medical oncology (53.2%) and urology (46.8%). The majority were highly experienced (83.6% with ≥11 years in practice) and hospital- and academic-based (66.4% and 71.2%, respectively)
- Physicians abstracted information from the medical records of 765 adult patients with MIBC planned for RC, of whom 340 (44.4%) were cis-E and 425 (55.6%) were cis-IE
- Among cis-IE patients, the Galsky criteria most commonly contributing to ineligibility were impaired renal function (62.6%), ECOG PS ≥2 (37.2%), and NYHA class III+ heart failure (13.9%); grade ≥2 audiometric hearing loss and peripheral neuropathy were each present in fewer than 14% of cases

Patient demographics and clinical characteristics

- Demographic characteristics of patients with MIBC who planned for RC are reported in **Table 1**
- Both cis-E and cis-IE groups were predominantly male (~75%) with similar sex distributions (*P*=0.62)
- Compared with cis-E patients, cis-IE patients were significantly older (mean 64.5 ± 9.8 vs 61.9 ± 7.1 years; *P*<0.001)

Table 1. Demographic characteristics of patients with MIBC who planned for RC[a]

	Cisplatin-eligible N = 340	Cisplatin-ineligible N = 425	*P*-value
Age at date of planned RC, years			
Mean ± SD	61.9 ± 7.1	64.5 ± 9.8	<0.001*
Median (range)	61.6 (39.6, 82.2)	64.9 (18.8, 95.6)	
Sex, n (%)			0.62
Male	255 (75.0)	312 (73.4)	
Female	85 (25.0)	113 (26.6)	
Country of residence, n (%)			0.06
Germany	173 (50.9)	180 (42.4)	
France	91 (26.8)	131 (30.8)	
UK	76 (22.4)	114 (26.8)	
Smoking status			
Current/former smoker, n (%)	263 (77.4)	313 (73.6)	0.55
Smoking pack-years,[b] mean ± SD	29.4 ± 26.8	36.9 ± 27.5	0.02*
BMI, kg/m²			
Mean ± SD	25.6 ± 3.1	26.4 ± 6.0	0.03*
BMI category,[c] n (%)			0.43
Underweight	0 (0.0)	0 (0.0)	
Normal	104 (40.0)	103 (35.3)	
Overweight	141 (54.2)	167 (57.2)	
Obese	15 (5.8)	22 (7.5)	
Unknown	80	133	

BMI, body mass index; kg, kilogram; m, meter; MIBC, muscle-invasive bladder cancer; RC, radical cystectomy; SD, standard deviation; UK, United Kingdom.
Notes:
*Statistically significant at the α = 0.05 level.
[a]Patient demographic characteristics were assessed at, or closest to, the date of the planned RC.
[b]Assessed among current or former tobacco users.
[c]Patients with BMI <18.5 kg/m², 18.5-24.9 kg/m², 25-29.9 kg/m², and ≥30 kg/m² were classified as underweight, normal weight, overweight, and obese, respectively.

Clinical and disease characteristics

- Characteristics were assessed at, or closest to, the date of MIBC diagnosis and are summarized in **Table 2**
- ECOG PS differed markedly between groups: cis-E patients were predominantly ECOG PS 0 (60.0% vs 18.1% among cis-E patients), whereas 37.2% of cis-IE patients had ECOG PS ≥2 (vs 0% among cis-E patients). As ECOG PS ≥2 is a defining criterion for cisplatin ineligibility, these differences between groups are expected by design

Table 2. Clinical and disease characteristics of patients with MIBC who planned for RC[a]

	Cisplatin-eligible N = 340	Cisplatin-ineligible N = 425	*P*-value
Time from MIBC diagnosis to date of planned RC, months			
Mean ± SD	4.4 ± 2.7	3.7 ± 3.4	<0.001*
Median (range)	4.2 (0.0, 12.0)	2.3 (0.0, 12.0)	
Year of planned RC, n (%)			<0.01*
2010-2014	23 (6.8)	24 (5.6)	
2015-2019	251 (73.8)	278 (65.4)	
2020 or later	66 (19.4)	123 (28.9)	
Received planned RC, n (%)			0.22
Yes	328 (96.5)	402 (94.6)	
No	12 (3.5)	23 (5.4)	
Primary reason for failed RC,[b] n (%)			0.02*
Disease progression of MIBC precluding RC	5 (41.7)	13 (56.5)	
Medical reason (eg, comorbidity) precluding RC	6 (50.0)	3 (13.0)	
Patient declined procedure	0 (0.0)	6 (26.1)	
Residual disease and any radiographical disease present	0 (0.0)	1 (4.3)	
Death from any cause, prior to date of planned RC	0 (0.0)	0 (0.0)	
Other[c]	1 (8.3)	0 (0.0)	
Clinical TNM staging subgroups, n (%)			0.06
T2N0M0	132 (38.8)	138 (32.5)	
T3/T4aN0M0	95 (27.9)	111 (26.1)	
T1-T4aN1M0	113 (33.2)	176 (41.4)	
ECOG PS at MIBC diagnosis,[d] n (%)			–
0	204 (60.0)	77 (18.1)	
1	136 (40.0)	181 (42.6)	
2+	0 (0.0)	158 (37.2)	
Unknown	0	9	

ECOG PS, Eastern Cooperative Oncology Group Performance Status; MIBC, muscle-invasive bladder cancer; RC, radical cystectomy; SD, standard deviation; TNM, tumor, node, metastasis.
Notes:
*Statistically significant at the α = 0.05 level.
[a]Assessed among all patients – those who received and did not receive RC.
[b]Assessed among patients who failed to undergo the planned RC.
[c]Other primary reason the patient failed to undergo the planned RC included "delay in the organization of the operating room."
[d]No statistical comparison was performed for ECOG PS. As ECOG PS ≥2 is a component criterion used to determine cisplatin eligibility, differences between groups are guaranteed by design.

Comorbidities

- Cis-IE patients had a significantly higher comorbidity burden than cis-E patients across nearly all assessed conditions (**Table 3**)
- The mean number of select comorbidities was nearly twice as high in cis-IE patients (2.3 ± 1.6 vs 1.2 ± 1.1; *P*<0.001) than cis-E patients

Table 3. Comorbidities of patients with MIBC who planned for RC[a]

	Cisplatin-eligible N = 340	Cisplatin-ineligible N = 425	*P*-value
Number of select comorbidities[b]			
Mean ± SD	1.2 ± 1.1	2.3 ± 1.6	<0.001*
Median (range)	1.0 (0.0, 6.0)	2.0 (0.0, 9.0)	–
Comorbidities,[c] n (%)			
High blood pressure	131 (38.5)	206 (48.5)	<0.01*
Hypercholesterolemia	62 (18.2)	112 (26.4)	<0.01*
Diabetes	50 (14.7)	96 (22.6)	<0.01*
Diabetes without chronic complications	42 (12.4)	48 (11.3)	0.65
Diabetes with chronic complications	6 (1.8)	39 (9.2)	<0.001*
Unknown	2	9	
Chronic obstructive pulmonary disease	37 (10.9)	69 (16.2)	0.03*
Depression	33 (9.7)	56 (13.2)	0.14
Obesity	24 (7.1)	52 (12.2)	0.02*
Peripheral vascular disease	18 (5.3)	48 (11.3)	<0.01*
Myocardial infarction	10 (2.9)	46 (10.8)	<0.001*
Peptic ulcer disease	8 (2.4)	12 (2.8)	0.69
Renal insufficiency	7 (2.1)	127 (29.9)	<0.001*
Congestive heart failure	7 (2.1)	60 (14.1)	<0.001*
Rheumatologic disease	7 (2.1)	16 (3.8)	0.17
Deep vein thrombosis	5 (1.5)	21 (4.9)	<0.01*
Pulmonary embolism	4 (1.2)	18 (4.2)	0.01*
Cerebrovascular disease	3 (0.9)	16 (3.8)	0.01*
Liver disease	1 (0.3)	8 (1.9)	0.05*
Mild	1 (0.3)	7 (1.6)	0.08
Moderate	0 (0.0)	1 (0.2)	1.00
Dementia	1 (0.3)	6 (1.4)	0.14
Any malignancy (except malignant neoplasm of skin)	0 (0.0)	1 (0.2)	1.00
Leukemia	0 (0.0)	1 (0.2)	1.00
Metastatic solid tumor	0 (0.0)	1 (0.2)	1.00
Other	10 (2.9)	9 (2.1)	0.47
None of the above conditions	103 (30.3)	40 (9.4)	<0.001*

AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; MIBC, muscle-invasive bladder cancer; RC, radical cystectomy; SD, standard deviation.
Notes:
*Statistically significant at the α = 0.05 level.
[a]Comorbidities were assessed at, or closest to, the date of MIBC diagnosis.
[b]Select comorbidities include high blood pressure, hypercholesterolemia, diabetes, chronic obstructive pulmonary disease, depression, obesity, peripheral vascular disease, myocardial infarction, peptic ulcer disease, renal insufficiency, congestive heart failure, rheumatologic disease, deep vein thrombosis, pulmonary embolism, cerebrovascular disease, liver disease, dementia, any malignancy (except malignant neoplasm of skin), metastatic solid tumor, hemiplegia or paraplegia, and HIV/AIDS.
[c]Categories are not mutually exclusive.

Treatment patterns

- Treatment patterns by cisplatin eligibility are summarized in **Table 4**
- RC was performed in nearly all patients: 96.5% of cis-E and 94.6% of cis-IE
- Compared with cis-E patients, cis-IE patients were less likely to receive neoadjuvant therapy (22.1% vs 67.9%) and more likely to undergo surgery alone (without neoadjuvant or adjuvant therapies; 42.6% vs 20.6%)

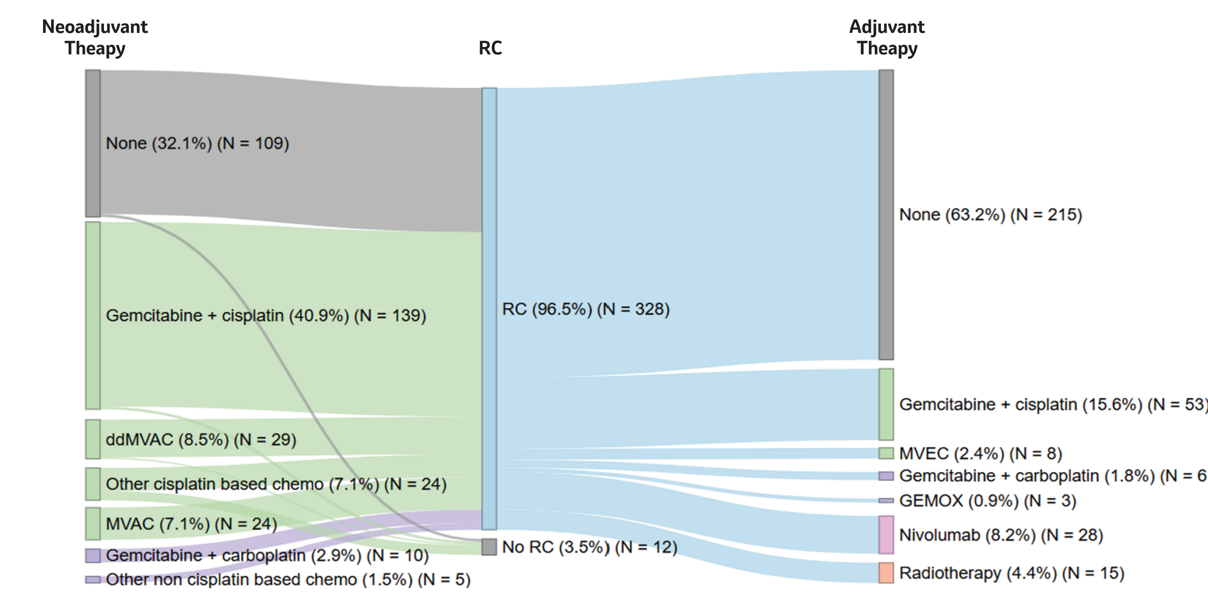
Table 4. Treatment patterns for patients with MIBC who planned for RC

	Cisplatin-eligible N = 340	Cisplatin-ineligible N = 425
Received neoadjuvant therapy, n (%)	**231 (67.9)**	**94 (22.1)**
Received RC, n (%)	**328 (96.5)**	**402 (94.6)**
Time from MIBC diagnosis to RC,[a] months, median (range)	4.1 (0.0, 12.0)	2.3 (0.0, 12.0)
Treatment patterns among patients who received RC, n (%)		
RC alone	70 (20.6)	181 (42.6)
Neoadjuvant therapy + RC	143 (42.1)	53 (12.5)
RC + adjuvant therapy[b]	37 (10.9)	131 (30.8)
Neoadjuvant therapy + RC + adjuvant therapy[b]	78 (22.9)	37 (8.7)

MIBC, muscle-invasive bladder cancer; PD-L1, Programmed death-ligand 1; RC, radical cystectomy.
Notes:
[a]Assessed only among patients who received RC.
[b]Only patients who received RC were eligible to receive adjuvant therapy. European approval (2022) of adjuvant nivolumab for high-risk muscle-invasive bladder cancer is limited to tumors with PD-L1 ≥1%.

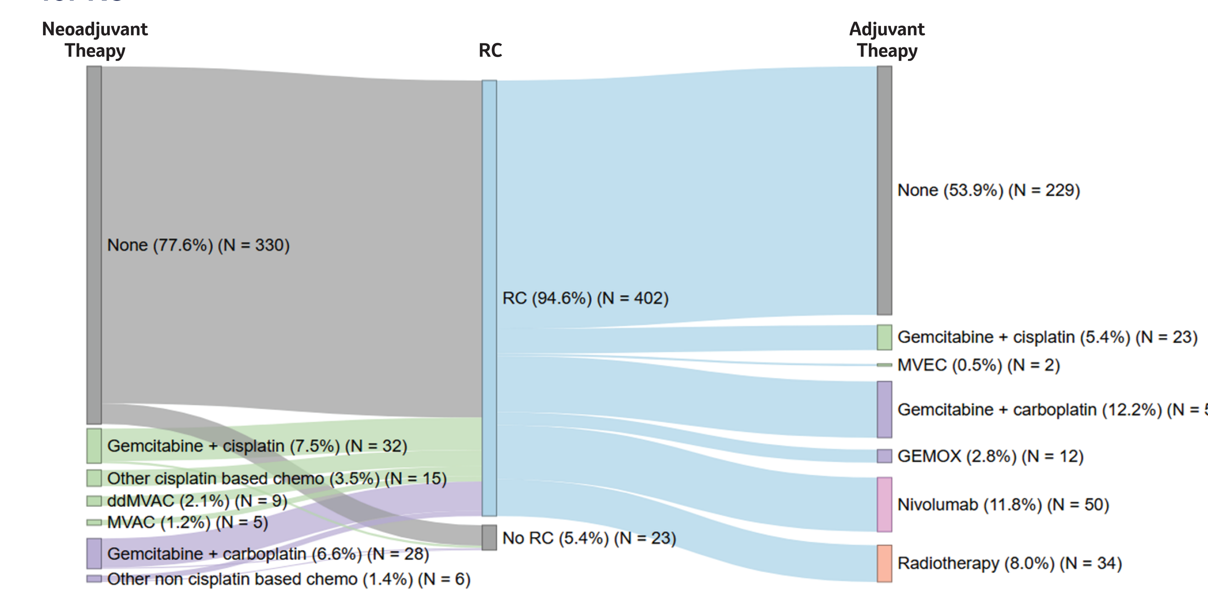
- Neoadjuvant and adjuvant treatment patterns differed markedly by cisplatin eligibility (**Figure 1**, **Figure 2**)
- Among cis-E patients, the predominant treatment patterns (**Figure 1**) was RC preceded by neoadjuvant chemotherapy, most commonly GC (40.9%), with most patients not receiving subsequent adjuvant therapy (63.2%)
- In contrast, among cis-IE patients, RC alone without perioperative systemic therapy was the most common treatment pattern (**Figure 2**), with 77.6% receiving no neoadjuvant treatment and 53.9% receiving no adjuvant treatment

Figure 1. Treatment patterns among cisplatin-eligible patients with MIBC who planned for RC



Chemo, chemotherapy; ddMVAC, dose-dense MVAC; GC, gastric cancer; GEMOX, gemcitabine + oxaliplatin; MIBC, muscle-invasive bladder cancer; MVAC, methotrexate, vinblastine, doxorubicin, and cisplatin; MVEC, methotrexate + vinblastine + epirubicin + cisplatin; RC, radical cystectomy; PD-L1, Programmed death-ligand 1.
Notes:
[a]Other cisplatin-based chemotherapies include therapies, or combinations of therapies, not listed in the diagram (ie, gemcitabine + cisplatin, ddMVAC, MVAC, and MVEC). These therapies include cisplatin + methotrexate + vinblastine (CMV); cyclophosphamide + doxorubicin + cisplatin (CAP); cisplatin + methotrexate (CM); cisplatin monotherapy; and gemcitabine + cisplatin + paclitaxel (GCP).
[b]Other non–cisplatin-based chemotherapies include therapies, or combinations of therapies, not listed in the diagram (ie, gemcitabine + carboplatin and GEMOX). These therapies include carboplatin monotherapy and gemcitabine + oxaliplatin + nab-paclitaxel (GON).
[c]In the adjuvant therapy setting, other immunotherapies were administered, including avelumab, atezolizumab, and pembrolizumab, in combination with the listed therapies (eg, GC, radiotherapy).
[d]European approval (2022) of adjuvant nivolumab for high-risk muscle-invasive bladder cancer is limited to tumors with PD-L1 ≥1%.

Figure 2. Treatment patterns among cisplatin-ineligible patients with MIBC who planned for RC



Chemo, chemotherapy; ddMVAC, dose-dense MVAC; MIBC, muscle-invasive bladder cancer; GEMOX, gemcitabine + oxaliplatin; MVAC, methotrexate, vinblastine, doxorubicin, and cisplatin; MVEC, methotrexate + vinblastine + epirubicin + cisplatin; RC, radical cystectomy.
Notes:
[a]Other cisplatin-based chemotherapies include therapies, or combinations of therapies, not listed in the diagram (ie, gemcitabine + cisplatin, ddMVAC, MVAC, and MVEC). These therapies include cisplatin + methotrexate + vinblastine (CMV); cyclophosphamide + doxorubicin + cisplatin (CAP); cisplatin + methotrexate (CM); cisplatin monotherapy; and gemcitabine + cisplatin + paclitaxel (GCP).
[b]Other non–cisplatin-based chemotherapies include therapies, or combinations of therapies, not listed in the diagram (ie, gemcitabine + carboplatin and GEMOX). These therapies include carboplatin monotherapy and gemcitabine + oxaliplatin + nab-paclitaxel (GON).
[c]European approval (2022) of adjuvant nivolumab for high-risk muscle-invasive cancer is limited to tumors with PD-L1 ≥1%.

Strengths & Limitations

- Strengths: Large, multi-country study using real-world data (France, Germany, UK) with detailed chart abstraction and standardized application of Galsky criteria, which is among the first studies to describe and compare cis-E vs cis-IE patients with MIBC in routine European practice
- Limitations: Retrospective, observational design, and physician-reported data introduce risks of selection bias, residual confounding, and potential misclassification of cisplatin eligibility; findings may not generalize beyond the included European countries

Conclusions

- In this real-world European cohort using Galsky criteria, cis-IE patients were significantly older, had more comorbidities, and were far less likely to receive perioperative systemic therapy (neoadjuvant or adjuvant) despite planned curative intent surgery
- There is an urgent need for new therapies that prevent recurrence and improve overall survival, especially for cis-IE patients. Timely adoption of novel, effective treatments for all patients with MIBC with intent to undergo RC is warranted to optimize patient outcomes

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