

Use of inpatient systemic chemotherapy and/or radiotherapy and related predictive factors for metastatic urothelial cancer: findings from a retrospective observational study in a clinical practice setting in Italy

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SCOPE



- This study describes the treatment rate and related predictive factors, demographics, and clinical characteristics of patients with metastatic urothelial cancer (mUC) who did or did not receive systemic chemotherapy and/or radiotherapy in the inpatient setting in Italy
- Another poster (poster no. EE533) describes the related healthcare resource utilization and costs¹

CONCLUSIONS



- The findings of this real-world 2017-2018 retrospective longitudinal cohort study indicate that nearly three-fourths of patients with mUC did not receive inpatient systemic chemotherapy and/or radiotherapy in Italy; driving factors were older age, female sex, and high comorbidity burden
- Although this study provides a partial capture of systemic therapy use in Italy, the results are consistent with those of other European studies with similar designs
- Additional research is needed to determine whether treatment rates have improved with the addition of novel therapies to the mUC treatment armamentarium

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BACKGROUND

- Bladder cancer is the tenth most commonly diagnosed cancer globally, with urothelial cancer (UC) accounting for almost 90% of all cases^{2,3}
- In 2022 in Italy, there were 313,600 cases of bladder cancer, and approximately 29,200 new diagnoses were estimated⁴
- Approximately 20% of patients with UC present with surgically unresectable or de novo mUC⁵
- The survival rate is poor, with median survival of 3-6 months if left untreated⁶
- Use of immune checkpoint inhibitors as first-line treatment, first-line maintenance, and second-line treatment for patients with locally advanced or mUC has brought about significant changes in treatment strategy⁷

- A recent literature search and meta-analysis study revealed that a substantial proportion of patients with locally advanced or mUC do not receive any systemic drug treatment⁸
- In this rapidly evolving treatment landscape, understanding the treatment rate and related predictive factors of receiving systemic therapy (or not) is therefore of utmost importance for better management of patients with locally advanced or mUC

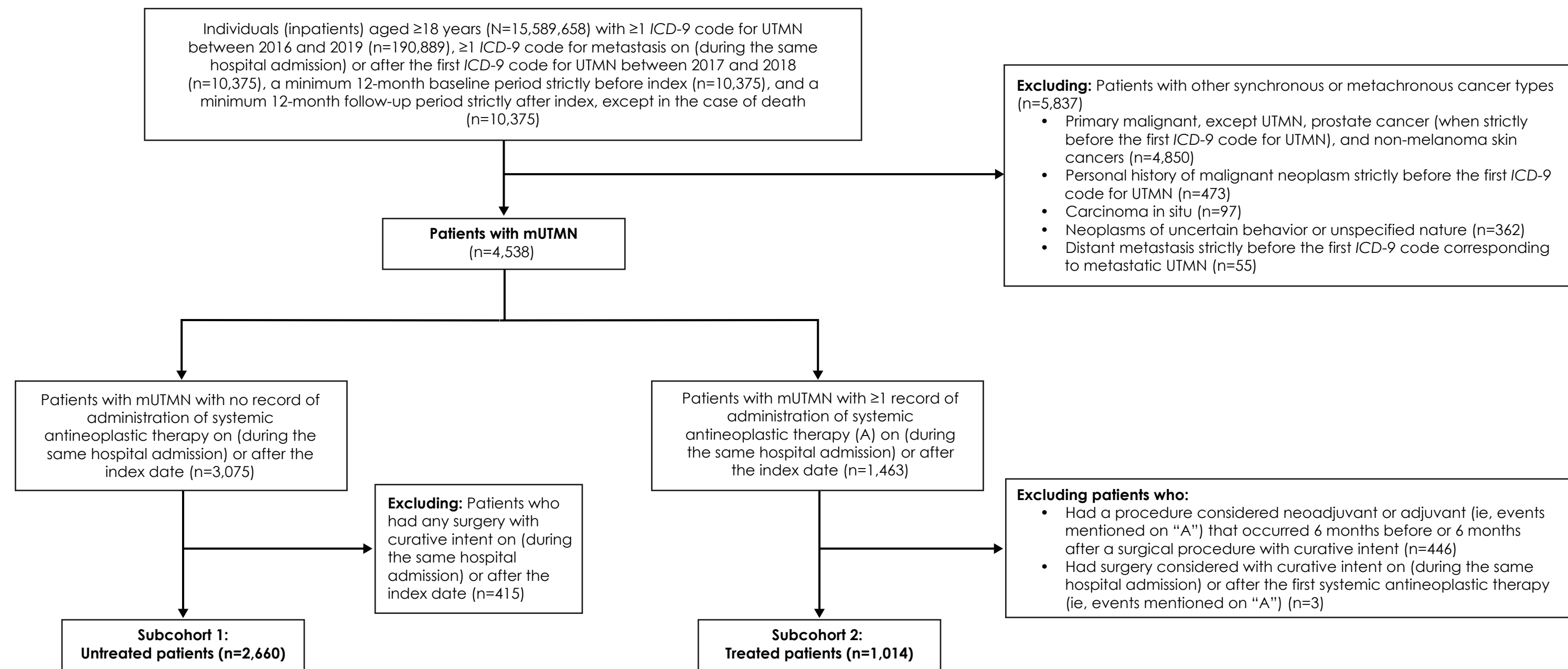
METHODS

- This retrospective observational analysis used the nationwide hospital discharge database (Scheda di Dimissione Ospedaliera) to describe incident adult (age ≥18 years) patients with a first hospitalization for mUC (index) between 2017 and 2018 (baseline period: 2016, follow-up: 2019), identified by a combination of *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)*, medical procedure, and diagnosis-related group codes
- A multivariable logistic regression model was fitted to identify factors associated with receiving inpatient chemotherapy and/or radiotherapy (or not). Age (as a continuous variable), sex, Charlson Comorbidity Index (CCI) score (as a continuous variable), region of the hospital facility, diabetes, urinary tract infection, and acute renal failure showed statistical significance at the univariate level and were therefore considered as potential predictive factors at the multivariable level

RESULTS

- A total of 3,674 patients with mUC were identified, of whom 27.6% were treated with inpatient chemotherapy and/or radiotherapy and 72.4% with neither (**Figure 1**)
- In treated and untreated patients, respectively, the median age at index was 71.0 and 78.0 years, 36.2% and 61.5% were ≥75 years old, and the mean (SD) CCI score was 0.3 (0.8) and 0.6 (1.1). The primary tumor location was bladder in 87.2% of patients (**Table 1**)
- Cardiovascular disease and renal function impairment were more prevalent in untreated patients (22.6% and 13.2%, respectively) than in treated patients (16.7% and 7.8%, respectively) (**Table 2**)
- Older age (odds ratio, 0.94 [95% CI, 0.93-0.95]), female sex (0.82 [0.68-0.99]), and higher CCI score (0.83 [0.73-0.93]) were all associated with a lower likelihood of receiving inpatient chemotherapy and/or radiotherapy (**Table 3**)

Figure 1. Patient flowchart of cohort definition, including treatment rate



ICD-9, International Classification of Diseases, Ninth Revision; mUTMN, metastatic urinary tract malignant neoplasm.

Table 1. Patients' baseline characteristics

		Total population (N=3,674)	Treated (n=1,014)	Untreated (n=2,660)
Age at index date, years	Mean (SD)	74.5 (10.3)	69.9 (9.8)	76.3 (9.9)
	Median (Q1; Q3)	76.0 (68.0; 82.0)	71.0 (64.0; 77.0)	78.0 (70.0; 84.0)
Age groups at index date, n (%)	Range	35.0-99.0	36.0-95.0	35.0-99.0
	<65 years	626 (17.0)	276 (27.2)	350 (13.2)
	65-69 years	446 (12.1)	178 (17.6)	268 (10.1)
	70-74 years	600 (16.3)	193 (19.0)	407 (15.3)
	75-79 years	741 (20.2)	209 (20.6)	532 (20.0)
	80-84 years	660 (18.0)	123 (12.1)	537 (20.2)
	≥85 years	601 (16.4)	35 (3.5)	566 (21.3)
Sex, n (%)	Male	2,813 (76.6)	797 (78.6)	2,016 (75.8)
	Female	861 (23.4)	217 (21.4)	644 (24.2)
Charlson Comorbidity Index score	Mean (SD)	0.5 (1.0)	0.3 (0.8)	0.6 (1.1)
	Median (Q1; Q3)	0 (0; 1.0)	0 (0; 0)	0 (0; 1.0)
Localization of primary UC, n (%)	Bladder	3,203 (87.2)	888 (87.6)	2,315 (87.0)
	Ureter	220 (6.0)	59 (5.8)	161 (6.1)
	Renal pelvis	251 (6.8)	67 (6.6)	184 (6.9)

Q, quartile; UC, urothelial cancer.

Table 2. Selected comorbidities of interest

Comorbidity [ICD-9-CM codes], n (%)	Total population (N=3,674)	Treated (n=1,014)	Untreated (n=2,660)
Cardiovascular disease [390-459]	771 (21.0)	169 (16.7)	602 (22.6)
Diabetes mellitus [250.*]	189 (5.1)	52 (5.1)	137 (5.2)
Gastrointestinal disease [520-579]	308 (8.4)	67 (6.6)	241 (9.1)
Renal function impairment [584-586, 572.4]	431 (11.7)	79 (7.8)	352 (13.2)
Respiratory disease [460-519]	364 (9.9)	81 (8.0)	283 (10.6)
Heart failure [428.*]	102 (2.8)	10 (1.0)	92 (3.5)
Hearing loss [389.*]	3 (0.1)	1 (0.1)	2 (0.1)
Peripheral neuropathy [354.5, 356.0, 357.*]	5 (0.1)	1 (0.1)	4 (0.2)

ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.

Table 3. Predictive factors of receiving or not receiving systemic chemotherapy and/or radiotherapy

Variable	Odds ratio	SE	Z score	p value
Intercept	30.071	0.298	11.40651	<0.001
Age*	0.941	0.004	-15.39096	<0.001
Sex (male=0, female=1)	0.817	0.096	-2.11262	0.035
Region: Northeast† (Northwest=0)	0.673	0.133	-2.98105	0.003
Region: Center‡ (Northwest=0)	2.330	0.107	7.93868	<0.001
Region: South§ (Northwest=0)	1.761	0.116	4.88641	<0.001
Region: Islands¶ (Northwest=0)	0.948	0.164	-0.32216	0.747
CCI score**	0.825	0.063	-3.02899	<0.001
Comorbidity: cardiovascular disease [ICD-9-CM code, 390-459]	0.813	0.131	-1.57431	0.115
Comorbidity: diabetes mellitus [ICD-9-CM code, 250.*]	1.577	0.212	2.15108	0.031
Comorbidity: urinary tract infection, site not specified [ICD-9-CM code, 599.0]	0.681	0.193	-1.99199	0.046
Comorbidity: acute posthemorrhagic anemia [ICD-9-CM code, 584.9]	0.691	0.196	-1.89211	0.058
Comorbidity: acute renal failure, unspecified [ICD-9-CM code, 285.1]	0.534	0.211	-2.97555	0.003
Comorbidity: hypertension, unspecified [ICD-9-CM code, 401.9]	1.453	0.211	1.76898	0.077

CCI, Charlson Comorbidity Index; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.

*Age was included as a continuous variable in the model. †Northeast: P.A. Trento, P.A. Bolzano, Friuli-Venezia Giulia, Veneto, Emilia-Romagna. ‡Northwest: Piemonte, Valle d'Aosta, Lombardia, Liguria. §Center: Toscana, Marche, Umbria, Lazio. ¶South: Abruzzo, Molise, Campania, Puglia, Basilicata, Calabria. ††Islands: Sicilia, Sardegna. **Due to the exclusion criteria, tumors were not included in the CCI score, except for non-melanoma malignant neoplasm of skin or prostate cancer. CCI score was included as a continuous variable in the model.

LIMITATIONS

- There is a minor risk of misclassification of disease status, as no data on the classification of malignant tumors are available in Italian claims data. Therefore, a proxy (based on ICD-9 codes provided by clinicians treating patients with mUC) was used to identify patients with mUC. The risk of other concomitant cancers was also addressed via an ICD-9-based proxy to exclude patients with other primary synchronous or metachronous cancers (except prostate cancer, if before UC, and non-melanoma skin cancer), which may explain the relatively low CCI score (metastatic solid tumors are assigned a score of 6 in the CCI calculation)
- Other limitations of this analysis include a lack of clinical outcome measures (common with administrative claims databases), resulting in the treated and untreated populations being defined using the presence or absence of a reimbursed claim for administration of chemotherapy or radiotherapy in the inpatient setting (ie, systemic therapy). Claims for drug dispensation were not considered
- This study did not include patients with mUC who were diagnosed or treated in the outpatient setting or patients who were never hospitalized for mUC

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