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Multicentric analysis of the influence of sex in patients with metastatic invasive urothelial cancer in Northern Spain

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INTRODUCTION

Concerns and recognition of the **impact that sex** can have on cancer susceptibility, progression, survival, toxicity, and response to treatments are increasing[1].

There is evidence of **differences in urothelial cancer between men and women**. The results obtained from both real-world data and clinical trials (CTs) are contradictory, showing worse overall survival data for women treated in CTs. However, other studies show no differences based on sex[2,3].

AIM

The primary objective of this study is to analyze, using real-world data, the **influence of sex** on staging, rate of toxicities, and survival outcomes in patients diagnosed with invasive urothelial carcinoma (UC). Specifically, it aims to explore whether there are significant **differences in survival rates**, understood as overall survival and progression-free survival following treatment.

Ultimately, the findings could lead to **more personalized treatment strategies** and improved clinical outcomes for patients of both sexes.

METHOD

Study design and population

We performed a cohort study including adult patients (≥18 years) diagnosed with locally advanced or metastatic UC (mUC) between 1/01/2007 and 31/12/2019 of hospitals in the north of Spain.

Clinical data were collected from health records. The study was approved by the Institutional Review Board and Ethics Committee of all the participant centers and informed consent was obtained.

Data collection

Epidemiological, histological type, tumor characteristics, sites of metastasis, treatment information and outcome data were collected.

Statistical analysis

Patient demographics and study characteristics were analyzed using descriptive statistics. Median Overall Survival (OS) and Progression-Free Survival (PFS) were calculated using the Kaplan-Meier method. Statistical analysis was conducted with IBM SPSS version 26.

RESULTS

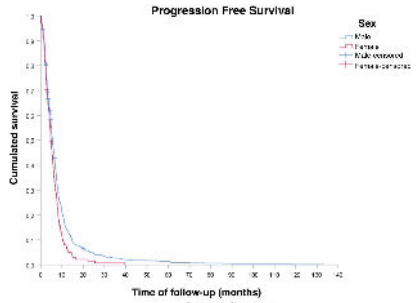
1230 patients were collected, of which 83.3% (n=1024) were men and 16.7% women (n=205)

In the table below, the baseline characteristics of the population are described, as well as the survival data.

Characteristics	Men (83.3%)	Women (16.7%)
Average age	67.4 years	65.9 years
Smoking rate	75.4%	42.4%
History of laUC	69.2%	66.8%
mRFS	12 months	11 months
Fit for platinum	53%	63.4%
Received 1st L for mUC	75.7%	77.1%
1st L treatment response rate	40.3% (10.4% CR)	35.5% (5.1% CR)
1st L treatment PFS	5.5 months	4.9.months (p < 0.01)
Hematologic toxicities in 1st L	18.9%	22.1%
Received 2nd L treatment	40%	40%
2nd L treatment response rate	16.3%	20%
2nd L treatment PFS	2.9 months	2.1 months
Received 3rd L treatment	17%	17%
Overall Survival	12.4 months	10.95 months (p < 0.01)

Table 1. Data summary *| laUC: Locally advanced urothelial cancer. mRFS: median relapse-free survival. mUC: Metastatic urothelial carcinoma. PFS: Progression-free survival. CR: Complete response*

1a



1b

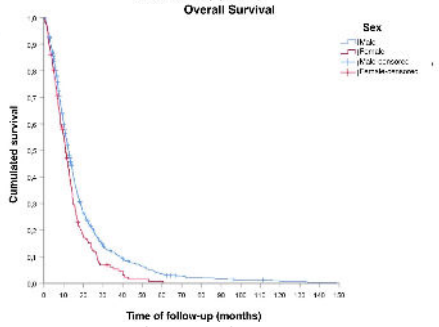


Image 1a. Kaplan-Meier of progression-free survival according to sex.
Image 1b. Kaplan-Meier of overall survival according to sex

CONCLUSIONS

The main difference observed in patients diagnosed with mUC in Northern Spain, consistent with available evidence, is a **higher incidence in men**.

Smoking rates were distinct between men and women, which could be a probable reason for a different tumorigenesis pathway.

In terms of efficacy, **women experienced worse PFS in the first line and worse OS**, likely due to delayed diagnosis from symptom onset to specialist referral. This should encourage greater awareness for prompt diagnosis of women presenting with urinary symptoms.

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