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Real-world data on management of muscle-invasive urothelial cancer in Spain in the era of adjuvant immunotherapy: the MINOTAURO study

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INTRODUCTION

Radical cystectomy combined with neoadjuvant (preferred) or adjuvant chemotherapy (CT) is still the standard treatment for muscle invasive bladder cancer[1].

On February 24th, 2022, EMA approved adjuvant nivolumab for patients with muscle invasive urothelial carcinoma (MIUC) and PD-L1 expression ≥1% and high risk of recurrence[2].

However, data on perioperative treatment use in Spain are limited.

AIM

This study aimed to characterize the demographics, clinical features, treatment patterns, and real-word outcomes of MIUC patients during the adjuvant immunotherapy era.

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METHOD

A multicenter, retrospective, observational study that included patient information from 17 hospitals across the North and East of Spain, diagnosed with T2-T4, N0-N3, M0 MIUC between April 1, 2022, and June 30, 2024.

Data were obtained from medical records, and patients were followed from diagnosis to last contact or death. The study was approved by an institutional review board.

The study data were collected and managed using the REDCap electronic data capture tool hosted on IDIVAL[3]

RESULTS

A total of 629 patients were included, with a mean age of 71 years of age (41-95); 80% were male and 74% were current/former smokers. Most tumors originated in the bladder (94%), had predominantly urothelial histology (93%) and were stage II (70%). About two thirds (63%) were CDDP eligible, of whom 73% received neoadjuvant CT (NACT) with CDDP + gemcitabine (66%) and ddMVAC (22%) as the most common regimes used. Seventy-eight per cent underwent surgery [95% ileal conduit], 10% completed trimodal therapy and 7% progressed after neoadjuvant CT. The pCR and downstaging rates after NACT were 27% and 33% respectively. The use of adjuvant CT was scarce (11%). Of those eligible for IO-based adjuvant treatment according to EMA criteria (n=207), 77 (37%) received an adjuvant CPI, being nivolumab the most common.

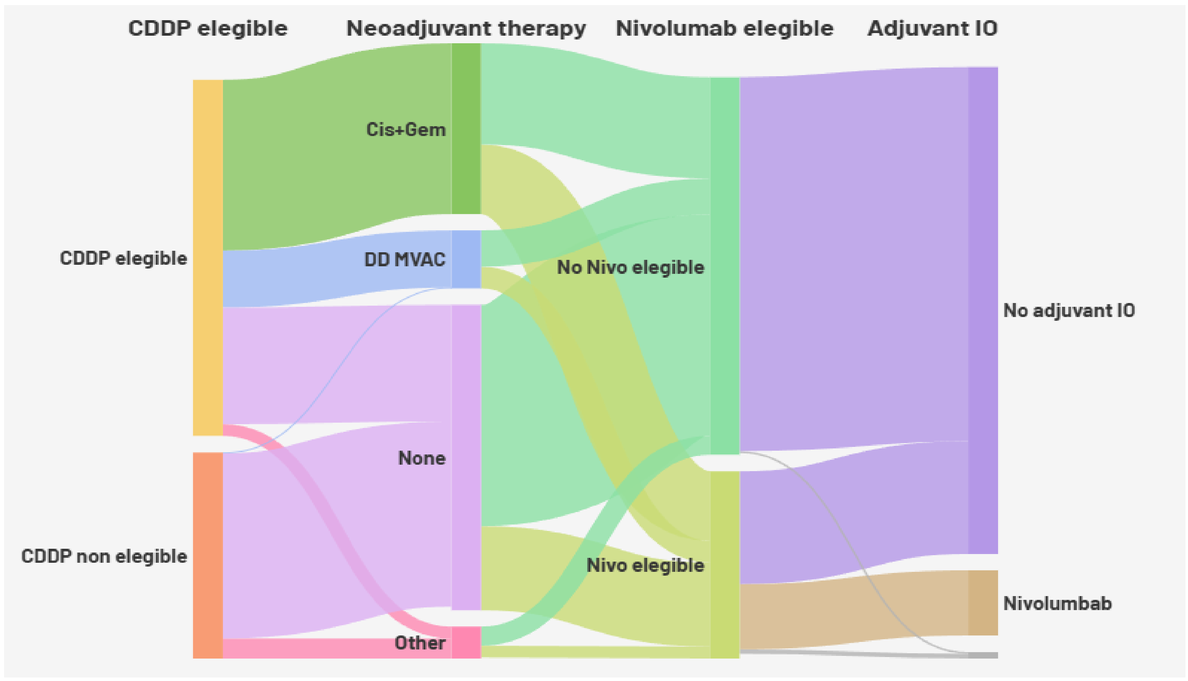

Fig. 1 Sankey diagram of the use of neoadjuvant chemotherapy and adjuvant immunotherapy

CONCLUSIONS

In this contemporary Spanish cohort of patients with MIUC, NACT followed by cystectomy remains the preferred treatment, with very few patients considered for trimodal therapy. Notably, NACT use is higher than in historical series, while adjuvant chemotherapy and in particular adjuvant immunotherapy seem to remain underutilized. pCR rates are aligned with outcomes from other large NACT series.

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