**Novel prognostic score for patients with metastatic bladder cancer on immunotherapy**

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**Background**

Some patients with metastatic bladder cancer (mBC) have durable responses to immune checkpoint inhibitors (ICIs); others progress early while suffering from autoimmune toxicity. Currently there is no prognostic score or tumour marker to predict who will benefit from ICIs in bladder cancer.

We designed a novel prognostic score to stratify response to ICIs in patients with mBC.

**Methods**

We analysed data from patients with mBC receiving ICIs as second- or later-line treatment between 2013–2023. We assessed key patient characteristics and their impact on progression-free survival (PFS) and overall survival (OS) using Kaplan-Meier and Cox-regression methods (retained if p<0.05). Variables independently correlated with OS and PFS on multivariate analysis were selected to create a new scoring model. Radiological response to ICIs was assessed. C-statistic was calculated to assess the model’s fit.

**Results**

149 patients with mBC were identified as having received second- or later-line ICIs. Median OS was 9.3 months and PFS 2.5 months. On multivariate analysis, absent liver and bone metastases, haemoglobin≥100g/L, ALP≤130 unit/L, NLR>5, and time from last therapy ≥6 months were independently associated with improved OS and PFS.

Using these variables, we created a 3-tier model that strongly correlated with OS (HR 2.0, 95% CI 1.4–2.4, p<0.001) and PFS (HR 1.7, 95% CI 1.2–2.0, p<0.001). Median OS for patients with 0-1, 2 and 3-5 risk factors was 24.2, 6.7, and 2.4 months, respectively. Complete or partial response was seen in 45.8%, 21.2%, and 6.5%, respectively. Disease control was seen in 62.5%, 39.4%, and 10.9% respectively.

This model achieved a C-statistic of 0.70 (95% CI 0.65-0.75).

**Conclusions**

ICIs with enfortumab vedotin will become first-line therapy for most patients with mBC. We used routinely available metrics to develop a new 3-tier model that strongly stratifies outcomes of patients with mBC receiving second- or later-line ICIs. The model requires external validation.

*300 words*

**Figure**

![A graph showing the number of factors in survival

Description automatically generated with medium confidence]()