EFFECTIVENESS OF COMBINATION GEMCITABINE/PACLITAXEL AFTER FAILURE OF PLATINUM-BASED CHEMOTHERAPY FOR METASTATIC UROTHELIAL CANCER

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Aim: For patients with metastatic urothelial cancer, overall survival is poor after progression from first-line chemotherapy (CT). In Europe, vinflunine is the only approved drug for second-line treatment – however, in Portugal, it has not been approved for reimbursement. Several phase II studies using gemcitabine and paclitaxel (GPac) have shown it to be an active and well tolerated second-line regimen. Our aim is to assess the effectiveness of the GPac regimen after failure of platinum-based CT.

Methods: Consecutive series of patients with metastatic urothelial cancer, who experienced progression during or after platinum-based CT and were subsequently treated with GPac, at our center, from January 2007 to December 2013. Data on demographics, prognostic factors, response, survival and toxicity were extracted from clinical files.

Results: Twenty five patients were included. Baseline characteristics: median age 63 years (range 48 – 78), 96% males, 12% ECOG performance status (PS) 0 and 88% PS 1 or 2, 20% hemoglobin level < 10 g/dL and 40% had visceral metastasis. Median time between the end of the platinum-based CT and GPac regimen was 5 months (range 0 – 28). The median number of cycles of GPac was 5 (range 1 – 10). Two patients (8%) had complete response. Median follow-up time, for patients alive at last follow up was 57 months. Median survival was 8 months (95% CI 5.1 – 10.9) and 12 month survival rate was 36% (95% CI 16.4 – 55.6). There were 5 patients surviving > 24 months. Of known prognostic factor, only presence of liver metastasis was a predictor of a poorer prognosis. Grade 3 – 4 toxicity was identified in 88% of patients: neutropenia (60%), thrombocytopenia (56%), anemia (16%) and sepsis (12%).

Conclusions: GPac was active, with 8% complete responses and durable remissions in 24% of patients. Toxicity, although high, was manageable.

Disclosure: All authors have declared no conflicts of interest.