Abstract Code: IUC26652-86

Clinical impact and safety profile of Enfortumab-vedotin: evaluate the efficacy and safety outcomes obtained in patients diagnosed with metastatic urothelial carcinoma undergoing treatment with Enfortumab Vedotin.

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OBJECTIVES:

To evaluate the efficacy and safety outcomes obtained in patients diagnosed with metastatic urothelial carcinoma undergoing treatment with Enfortumab Vedotin.

MATERIALS AND METHODS:

An observational, descriptive, and retrospective study was conducted, registering all patients with metastatic urothelial carcinoma treated with Enfortumab Vedotin at our hospital since its approval. Data were obtained through electronic medical records and the electronic prescription program for outpatients. The Office21 and SPSS28 software packages were used for statistical analysis.

RESULTS:

A total of 10 patients were included, with a mean age of 73.1+/-5.6years. 100% were male and presented a mean weight of 82.2+/- 13.7kg. Regarding metastases, the most prominent were pulmonary at 70%(7/10), bone at 40%(4/10), and hepatic at 30%(3/10). The median number of prior lines of therapy was 2(1–4), with the most frequently used regimens being gemcitabine+platinum in 100%(carboplatin 50% and cisplatin 50%), followed by immunotherapy: avelumab 60%(6/10) and atezolizumab 30%(3/10), and finally, paclitaxel 10%(1/10). 30%(3/10) received subsequent treatment, which was different for each patient: vinflunine, docetaxel, and retreatment with gemcitabine+carboplatin. The median follow-up was 4.5(IQR 2.5–10.5) months. The median number of doses received was 6(IQR 3–14). 70%(7/10) experienced a dose reduction to 1 mg/kg. A PFS of 4 months from the start of

treatment was obtained. 40%(4/10) still remain on treatment and 60% discontinued, with 30%(3/10) due to progression and the other 30% due to poor tolerance. Regarding safety, the regimen presented toxicity in 90% (9/10). A total of 32 ADRs were recorded, of which 71.9%(23/32) were grade 1 and 28.1%(9/32) were grade 2. The most frequently reported were: infections (18.8%), rash (12.5%), neutropenia, asthenia, hypertransaminasemia (9.4%), dyspnea, decreased appetite, and neutropenia (6.3%), anemia, thrombopenia, dysphagia, bleeding, hyperglycemia, and hypoacusis (3.1%). Additionally, exitus was reported in 50%.

CONCLUSIONS:

Enfortumab Vedotin offers a clinical benefit in heavily pretreated patients with metastatic urothelial carcinoma, achieving a median real-world progression-free survival of 4 months. Although the incidence of toxicity is very high, it remains within mild-to-moderate grades. The high frequency of dose reductions and discontinuations due to intolerance highlights the importance of specialized pharmaceutical care in the early detection and management of adverse reactions.