Vinflunine in routine clinical practice for the treatment of advanced or metastatic urothelial cell carcinoma - data from a prospective, multicenter experience.

Vinflunine is recommended in the European guideline for the treatment of advanced or metastatic urothelial cell carcinoma (UCC) after failure of platinum-based therapy. This prospective, non-interventional study investigated the safety and efficacy of vinflunine in platinum-pretreated UCC patients in routine clinical practice. Data were prospectively collected on patients with advanced or metastatic UCC undergoing vinflunine treatment in 39 German hospitals and medical practices. Dosing of vinflunine, tumor assessments and concomitant medications followed physician's routine clinical practice. Primary endpoints were toxicity and assessment of vinflunine treatment modalities. Secondary aims included overall response rate (ORR), overall survival (OS) time and a prognostic risk-model. Seventy-seven platinum-pretreated patients were recruited. Vinflunine was predominantly administered as second-line (66%) therapy or in subsequent treatment lines (21%). One third of the patients received at least six cycles of vinflunine and the average number was 4.7 cycles. A vinflunine starting dose of 320 mg/m² was chosen in 48% of patients and 280 mg/m² in 39%. Grade 3/4 toxicities were leucopenia 16.9%, anemia 6.5%, elevated liver enzymes 6.5% and constipation 5.2%. ORR was 23.4% and OS was 7.7 (CI 4.1 to
10.4) months. Patients with zero, one, two or $\geq$three risk factors displayed a median OS of 18.2, 9.5, 4.1 and 2.8 months, respectively (p=0.0005; HR=1.82). Vinflunine delivers a meaningful benefit to an unselected population of advanced platinum-pretreated UCC patients managed in routine clinical practice.

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