Session F. Genitourinary cancer

F46 New biomarkers of sunitinib efficacy in metastatic renal cell carcinoma

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Background: Hypertension, hypothyroidism, thrombocytopenia and neutropenia are frequent side effects of sunitinib. Preliminary studies suggested that drug-related toxicity may correlate with a better prognosis.

Material and methods: We retrospectively analyzed clinical records of patients (pts) affected by metastatic renal cell carcinoma (mRCC) treated with sunitinib as first-line therapy. We evaluated the following toxicities: hypertension (blood pressure >140/90 mmHg or blood pressure requiring intensification of a pre-existing anti-hypertensive medication), hypothyroidism (requiring hormone replacement therapy, with or without symptoms), thrombocytopenia (platelet count <100.000) and neutropenia (neutrophils <500). Overall survival (OS) and progression free survival (PFS) were calculated until 24 months of follow up. OS and PFS in patients who developed and who did not develop a drug-related toxicity were compared using T-test and \( X^2 \) or Fisher exact test.

Results: Thirty pts (19 males), median age 70.4 years, were evaluated; 20 pts (66%) had pre-existing controlled hypertension and four pts (13.3%) pre-existing hypothyroidism (in therapy). Complete blood count was normal in all the pts before starting the treatment. Twenty-two pts (73.3%) experienced at least one toxicity: 14 pts (46.6%) developed hypothyroidism, 8 pts (26.6%) hypertension that required medical therapy, 13 pts (43%) thrombocytopenia and 2 pts (6.6%) neutropenia. We found that median OS and median PFS of pts who developed hypothyroidism was 21.6 vs 12.8 months (p = 0.04), and 13.7 vs 8 months (p = 0.064), respectively. Median OS and median PFS of pts who developed hypertension was 22.3 vs 14.7 months (p = 0.028), and 16.5 vs 8.8 months (p = 0.023), respectively. No significant difference in OS and PFS was found in pts who developed only thrombocytopenia or neutropenia (probably due to the small number of patients included). Median OS and median PFS were significantly longer in patients who developed at least one toxicity vs patients who did not: 20.5 vs 8 months (p = 0.0001) and 12.7 vs 6.7 months (p = 0.088), respectively.

Conclusions: In patients with mRCC treated with sunitinib, the development of drug-related toxicity, in particular hypertension and hypothyroidism appeared associated with a longer OS and PFS. Other studies are necessary to confirm our preliminary findings.