Incidence of thyroid hormone therapy in patients treated with sorafenib or sunitinib

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Background: The multi-kinase inhibitors (MKI) sorafenib and sunitinib have been approved for treatment of various types of cancer since 2006. Both MKI can induce serious adverse drug reactions (ADR) such as hypothyroidism. The incidence of ADRs, however, has not been reliably determined in clinical trials.

Objectives: To determine incidence and relative risk of thyroid hormone therapy in patients treated with sorafenib or sunitinib.

Methods: A retrospective cohort study was performed using claims data for ambulatory prescriptions within the statutory health insurance scheme covering >80% of German community pharmacies.

Setting: Patients with a first prescription (index) of sorafenib or sunitinib in the period 7/2006 – 12/2007 were followed until drop-out of database, discontinuation or switch of MKI therapy, a prescription of antithyroid drugs, or the end of follow-up (8/2008). Patients treated with thyroid hormones (TH) 12 months before or within 29 days from the index date were excluded.

Main outcome measures: Incident prescription of any TH.

Statistical analysis: Incidence rates were calculated from the number of cases divided by the sum of follow-up times. Univariate and multivariate proportional hazards models were used to compare both cohorts.

Results: 77 of 1,214 patients (6.3%) treated with sorafenib versus 178 of 1,295 (13.7%) treated with sunitinib received TH. Incidence rates were 12.1 and 24.1 per 100 person-years, respectively. Unadjusted hazard ratio (HR) for TH therapy was 1.98 (95% CI: 1.52-2.59) for sunitinib compared to sorafenib and remained significant after adjustment for covariates, i.e., type of prescriber, region, insurance status, health insurance company, index year, and co-medication: HR: 2.05 (1.56-2.69).

Conclusions: Patients treated with sunitinib have a 2-fold increased risk of requiring TH therapy compared to sorafenib.