A phase II study of sunitinib in patients with recurrent and/or metastatic non-nasopharyngeal head and neck cancer.

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Source

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Abstract

PURPOSE:

Patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (RM-SCCHN) bear a grave prognosis. There are unmet needs for the development of novel agents for this incurable disease. Angiogenesis is an important biological process in SCCHN. We, therefore, evaluated the activity and safety of sunitinib, an oral tyrosine kinase inhibitor that targets multiple receptors, in patients with RM-SCCHN.

PATIENTS AND METHODS:

Seventeen patients were treated with sunitinib 50 mg per day administrated in 4-week cycles followed by a rest period of 2 weeks. Sunitinib and SU012662 plasma levels were determined based on a validated liquid chromatography-tandem mass spectrometry method and pharmacokinetic data were fitted in a non-compartmental analysis.

RESULTS:

Totally, 28 6-week cycles of treatment with sunitinib were administered (median, 2 cycles). Only three patients demonstrated stabilization of the disease; therefore, the study had to be terminated prematurely due to futility. Grade 3 toxicities, apart from fatigue, were infrequent. Other frequently reported side effects were skin discoloration, neutropenia, and thrombocytopenia. Ten various bleeding complications were reported in seven patients. Mean maximum concentrations (C(max)) were reached during the first day of treatment for sunitinib at 38.98 (+ or - 22.66) ng/ml and for SU012662 at 11.12 (+ or - 24.57) ng/ml. Our results showed that SU012662 has a longer half-life and a larger volume of distribution than the parent drug sunitinib. None of the biological markers tested was of any prognostic value.

CONCLUSIONS:

According to our findings, sunitinib monotherapy was not proven active in RM-SCCHN, and no further development of the drug in this indication is warranted.