RESPONSE TO SORAFENIB IN ADVANCED METASTATIC THYROID CANCER

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Background/Purpose: To investigate the efficacy of *off-label* sorafenib indication in progressive radioiodine resistant metastatic thyroid carcinoma.
Methods: *Off-label* observational study. Sorafenib 400 mg twice daily. The primary endpoint was the objective RECIST score assessed on day 30 and every 12 weeks thereafter. Additional endpoints were duration of tumor response and changes in tumor marker (thyroglobulin) measured initially, at 4 weeks, and then every 4 weeks. Clinical benefit was defined as partial response (PR) or stable disease (SD). Mean therapy duration was 10 ± 3 months.
Results: Eight patients were included (7 papillary, 1 insular variant). The 8 patients meeting study criteria received sorafenib 400 mg orally twice a day until disease progression or unacceptable toxicity developed. One patient showed a partial response with tumour regression of -35%, 6 months after treatment beginning; 5 patients exhibited stable disease and 2 patients were not evaluable (only 3 months of treatment). Thyroglobulin decreased within 2 weeks in all patients with follicular derived thyroid cancer by 50 ± 23%. Adverse events: One patient died because of sudden death (congestive heart failure). This patient had suffered a previous miocardiopathy probably related to sorafenib which originated the withdrawal of the drug 9 months after starting. Other adverse events were: fatigue (n=3), diarrhea (n=3), hand-foot syndrome (n=1), rash (n=1), hair loss (n=1). Hypertension was not observed. In 2 patients sorafenib dose was reduced 400 mg/d and in two to 600 mg/d. Four patients are on full dosage (800 mg/d), 1 after 18 months of treatment.
Discussion & Conclusion: These data suggest a possible role for sorafenib in the treatment of progressive metastatic DTC