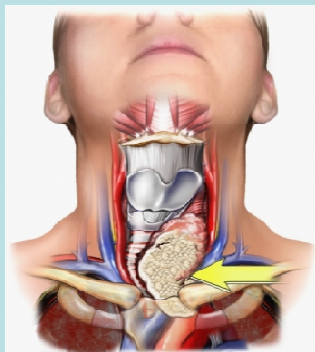


The use of sunitinib in metastatic thyroid carcinoma: case report of an off-label treatment.

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BACKGROUND



Thyroid cancer typically has a good outcome following standard treatments, which include surgery or radioactive iodine or systemic chemotherapies. In the last two years, many randomized trials demonstrated that multikinase inhibitors, such as sunitinib, are active in metastatic thyroid carcinoma. In Italy, sunitinib is only approved for the treatment of metastatic renal carcinoma, GIST or HCC, but a Sicilian regional law allows, in absence of valid therapeutic options, to the clinicians to prescribe an off label treatment and to the hospital pharmacies to distribute it.

PURPOSE: To evaluate the treatment of a multikinase inhibitor, sunitinib, for an off label indication and to assess the safety and efficacy of the treatment for an elderly patient, female, 80 years old, with metastatic thyroid cancer not responsive to cisplatin/epirubicin and gemcitabine.

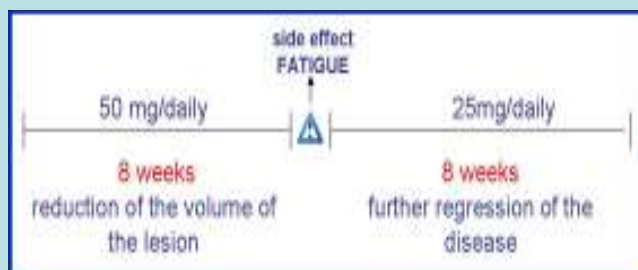
METHODS

The oncologist prepared a formal request, with patient's informed consent and all the phase II and III trials available in literature. This documents were also evaluated by the hospital pharmacist and then finally approved by the hospital medical director. After this procedure the pharmacy provided supplying and distributing the drug to the patient in domiciliary treatment.

RESULTS

Since April 2011, the patient assumed sunitinib at the standard dose of 50mg/day for 8 weeks and showed a reduction of the volume of the lesion.

The clinician made a constant and vigilant monitoring of hypertension. Fatigue was the side effect that leads to a reduction of dose to 25mg/day for other 8 weeks. Actually, six months later, a further regression of the disease is observed.



CONCLUSIONS:

Our data support the use of sunitinib in metastatic thyroid cancer, demonstrating also a low incidence of adverse reactions. This case report can prove the necessity to use also off label treatments if they are supported by valid clinical evidences either than to update the regulatory approvals of some drugs.