SUNITINIB AND SORAFENIB IN PATIENTS WITH METASTATIC RENAL CELL CANCER: ACCESS AND PERFORMANCE IN URUGUAY

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Introduction:

- In Uruguay, renal cell cancer (RCC) is the ninth and eleventh most common cancer in men and woman, respectively.
- Sunitinib and Sorafenib inhibit receptors of both vascular endothelial and platelet-derived, growth factor.
- Both are funded, with central and universal coverage, for metastatic RCC patients. A regulatory framework for coverage and a systematic process of evaluation were established. The criteria for treatment with Sunitinib and Sorafenib is shown in Table 1.

Objective: to assess the access, effectiveness and tolerance of Sunitinib and Sorafenib in metastatic RCC.

Methods: Cohort study of patients treated between January and December 2008. We assessed progression-free survival rates (PFS) and overall survival rates (OS) using the Kaplan-Meier method. Response rates were defined according to Response Evaluation Criteria in Solid Tumors (RECIST) criteria. Adverse effects were assessed according to the Common Terminology Criteria for Adverse Events v3.0 (CTCAE).

Table 1. INCLUSION CRITERIA FOR TREATMENT

Sunitinib (1st and 2nd line)	Sorafenib (2nd line)
Metastatic kidney cancer with clear cell component	Metastatic kidney cancer with clear cell component
Karnofsky 0-1	No response to interferon alpha or interleukin 2 after at least 3 months of treatment
LVEF (Left Ventricular Ejection Fraction) ≥ 55%	Cytokines intolerance
Humoral parameters within a normal range	LVEF > 55% Humoral parameters within a normal range

Results:

- Treatment was requested for 110 patients and was approved for 104 (94.5%).
- The request rate was 0.42/10000 for inhabitants over 14 years old. It was significantly lower for patients assisted at the public facilities compared with private (0.25 vs 0.64/10000 inhabitants, p<0.001), and for patients from the rest of the country compared with the capital (0.35 vs 0.52/10000 inhabitants, p=0.038).
- 84 patients (male 66.7%, 58 years) began the treatment before 1st October 2008. The median of followed-up and treatment were 8.5 and 6 months, respectively.
- Clinical response was documented in 33% of patients.
- Progress and death were reported in 11 and 28 patients, respectively. PFS and OS rates are shown in table 2.
- Treatment was stopped in 34.5% of patients; the main causes were disease progression in 13.1% and adverse effects in 10.7%.
- Adverse effects were reported in 64.5% of cases and in 41.7% they were grade III or IV.

Table 2

	SURVIVAL			
	3 months	6 months	9 months	12 months
Overall survival (n= 84)	88% (94,7-81,4)	74,2% (64,3-84,1)	63,1% (51,3-74,9)	56,1% (42,1-70,1)
Progression free survival (n= 80)	84,7% (93-76,7)	67,4% (78,2-56,6)	55,6% (68,1-43,1)	51,6 %(65,5-37,7)

Conclusions:

- Response rate, OS and PFS rates were similar to those internationally reported.
- Adverse effects were frequent and moderate to severe, and they caused patients to terminate treatment.
- Despite universal coverage, inequality in access probably persists and needs further investigation.