BEVACIZUMAB IN PATIENTS WITH METASTATIC COLORECTAL CANCER: ACCESS AND PERFORMANCE IN URUGUAY

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Introduction:

- In Uruguay, colorectal is the third most common cancer and the second leading cause of death from cancer.
- Bevacizumab is a recombinant humanized monoclonal antibody to vascular endothelial growth factor.
- It is funded, with centralized and universal coverage, for metastatic colorectal cancer patients in Uruguay. A regulatory framework for coverage and a systematic process of evaluation were established. The criteria for treatment with Bevacizumab in colorectal cancer is shown in Table 1.

Objective: to assess the access, effectiveness and tolerance of Bevacizumab associated with chemotherapy in patients with metastatic colorectal cancer in first or subsequent line of treatment in Uruguay.

Table 1. INCLUSION CRITERIA OF THE TREATMENT

Bevacizumab in Metastatic Colorectal Cancer
Colorectal cancer confirmed by histopathology
Metastatic disease confirmed by imaging study, and biopsy in case of only one image
Karnofsky scale value > 70%
Life expectancy of more than 3 months
Adequate clinical status than predict tolerance to treatment chemotherapy protocol

Methods:

Cohort study of patients treated with Bevacizumab between November 1st 2008 and December 31st, 2009. We assessed adverse effects, response rate, and progression-free survival (PFS) and overall survival (OS) using Kaplan-Meier method. Response rate was defined according to the Response Evaluation Criteria in Solid Tumors (RECIST).

Results:

- Treatment was requested for 254 patients and it was approved for 222 (87.4%).
- The request rate was 1/10,000 for inhabitants over 14 years old. It was significantly lower for patients assisted at the public facilities compared with private (0.52 vs 1.49/10000 inhabitants, p<0.001).
- 204 patients received the treatment and were followed-up for 15.5 months. Characteristics of patients are shown in Table 2.
- The clinical response occurred in 40% and the duration was 12 months.
- Progress and death were reported in 96 and 93 patients, respectively. OS and PFS rates are shown in Table 3.
- Median progression-free survival was 13.7 months (CI 95%, 12-16 months). In first line was 12.5 months (CI 95%, 11-14), in relapsed was 14.2 months (CI 95%, 8-21) and in progression was 8.9 months (CI 95%, 7-11).
- Overall survival was 16.3 months, without difference according to clinical situation or line of treatment.
  Adverse effects were reported in 30% of the patients and they forced to dose adjustment or suspension of the treatmen in 1.5% of cases.

Table 2

Characteristics	**Population N=204**
Age (years)	58 (range 21-78)
Female	47,5%
Time since diagnostic (month)	14,4 (range 4,9-26,5)
Metastasis > 1 site	47,1%
Metastasis site	
Hepatics only	39,2%
Lungs only	7,4%
Peritoneal only	6,4%
Hepatic and lungs associated	17,6%
Multiples in other sites	29,4%
Previous Tumor resection	87,7%
Metastasis resection	29,9%
Previous Radiotherapy	13,2%
First Line of treatment	53,9%
Previous Chemotherapy	80,9%
2 or more previous protocols	28,9%

Table 3. SURVIVAL RATES

	Survivals		
	3 months	6 months	12 months
Progression Free Survival N=203	91,8%	80,6%	48,9%
Overall Survival N=204	93,6%	88,6%	68,8%

Conclusions:

- Response rate and overall survival rate were similar to those internationally reported.
- Progression-free survival was longer than expected.
- Adverse effects rate was lower than reported, probably linked to underreporting.
- Despite universal coverage, inequality in access probably persists and needs further investigation.